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Part III

Department of Health, Education, and Welfare

Food and Drug Administration

Medical Devices; Classification of Neurological Devices

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 882

[Docket No. 78N-1000]

Neurological Devices; General Provisions

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule regarding general provisions applicable to the classification of neurological devices. The preamble to this rule responds to general comments received on the proposals regarding classification of neurological devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 28, 1978 (43 FR 55640), FDA published a proposed regulation containing general provisions applicable to the classification of neurological devices. The preamble to the regulation described the development of the proposed regulaitons classifying neurological devices and the activities of the Neurological Device Classification Panel, an FDA advisory committee that makes recommendations to FDA concerning the classification of neurological devices. FDA also published in that issue of the **Federal Register** individual proposed regulations to classify 103 neurological devices. FDA provided a period of 60 days for interested persons to submit written comments on these proposals.

Exemptions for Class I Devices

FDA proposed to exempt four devices from the good manufacturing practice (GMP) regulations in Part 820 (21 CFR Part 820), including the recordkeeping and reporting requirements of Part 820. The four devices are the two-point discriminator (Docket No. 78N-1003), the esthesiometer (Docket No. 78N-1017), the tuning fork (Docket No. 78N-1018), and the percussor (Docket No. 78N-1025). Elsewhere in this issue of the **Federal Register**, the agency is publishing final rules for classification of these four devices. The final rule for each of these devices exempts the device from all parts of the GMP requirements with the exception of §§ 820.180 and 820.198 (21 CFR 820.180 and 820.198) relating to records and complaint files. The agency has determined that exemption of devices from §§ 820.180 and 820.198 of the GMP regulation would not be in the public interest. Moreover, compliance with these sections is not unduly burdensome for device manufacturers. The complaint file requirements of § 820.198 ensures that device manufacturers have adequate systems for complaint investigation and followup. The general requirements concerning records in § 820.180 ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, can determine whether the manufacturer's corrective actions are adequate, and can determine whether an exemption from other sections of the GMP regulation, if one has been granted, is still appropriate.

Comments on Classification Proposals

Elsewhere in this issue of the **Federal Register**, FDA is issuing final regulations classifying 102 individual neurological devices. FDA is responding to specific comments regarding the classification of individual neurological devices in the final regulations for these devices.

No written comments were received on proposed § 882.1 (21 CFR 882.1), which concerns general provisions for all neurological devices. Accordingly, FDA is promulgating § 882.1 without change. However, FDA received several general comments regarding the classification process and the basis for the classification proposals for neurological devices. The agency is responding to these general comments below.

1. A comment stated that FDA did not always provide a sufficient explanation for the agency's proposal to classify a device and suggested that FDA relied too heavily on Panel experience and expertise. The Comment also stated that the supplemental information placed on file in the Hearing Clerk's office is not always readily available to interested persons. The comment suggested that, in future classification proposals, FDA should be more specific in setting forth the basis for its conclusions.

FDA believes that it provided an adequate explanation of the basis for each neurological device classification proposal. FDA relied on the recommendations of the Neurological Device Classification Panel and, in many cases, adopted the reasons given by the Panel as the basis for the proposed classification. It is apparent from the statute and from the legislative history of the Medical Device Amendments of 1976 (Pub. L. 94-295; 90 Stat. 539-583) that Congress intended FDA to rely on the advice of its device classification panels in deciding how to classify devices. Indeed, the House Committee that considered the legislation recognized that "data" supporting classification of devices was not intended to be limited to results of scientific experiments but should also include less formal evidence, other scientific information, or the judgments of experts. (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H. Rept. No. 94-853, 94th Congress, 2d. Session 40 (1976).) In many cases, FDA obtained additional information relevant to the classification of a device, summarized or cited this information in the proposal, and placed a copy of the information on file in the Hearing Clerk's office.

The agency does not believe that it is necessary for a classification proposal to include an exhaustive recitation of all data available on a device. When FDA obtained and relied on information in addition to, or other than, a Panel recommendation, the summary of the information in the proposal and the availability of the information in the Hearing Clerk's office, serve to inform interested persons of the basis for the proposed classification. This supplemental information is readily available to interested parties. In addition to being on public display in the Hearing Clerk's office, virtually all of the information is from the medical or scientific literature and is available in libraries.

The legislative history shows that Congress intended that the burden of providing evidence substantiating the safety and effectiveness of a medical device rests on the manufacturer (id.). A manufacturer who is dissatisfied with the data relied on by the Panel or by FDA in the classification proposal should submit any additional information that the manufacturer believes pertinent as part of its comments on the proposal.

2. Several comments stated that some neurological devices are similar or identical to devices that have been reviewed by other classification panels. One comment suggested that FDA postpone final classification of these neurological devices until the agency has published for comment the recommendations of the other panels

and the proposed regulations based on those recommendations.

FDA has attempted to do what the comment asks. Before publishing the neurological device classification proposals, FDA reviewed the recommendations from all of the classification panels to identify those devices reviewed by more than one panel. FDA found that 25 devices reviewed by the Neurological Device Classification Panel were essentially the same as devices reviewed by other classification panels. For 20 of these devices, FDA postponed publishing proposed classifications until the agency published the other panel's recommendations. For 5 neurological devices that also were reviewed by panels in addition to the Neurological Device Classification Panel, FDA published the Panels' recommendations as part of the proposals in the neurological device category.

FDA is continuing its efforts to consolidate panel recommendations concerning similar devices by attempting to identify these devices before publication of classification proposals, and by ensuring that each panel's recommendation is considered and published for comment before FDA promulgates final classification regulations for devices reviewed by more than one panel. In the **Federal Register** of March 6, 1979 (44 FR 12269), FDA published a notice of the availability of an index of classification regulations for medical devices. The index can be used by interested persons to determine the specific classification regulation for a device that was classified by more than one classification panel and to determine with which panel's classification regulations it will be published. FDA is, for instance, postponing publication of the final regulation for surgical sponges for internal use until after publication for comment of the recommendations on similar devices of the General and Plastic Surgery Device Classification Panel.

With respect to several neurological device classification proposals, FDA has changed the identification or name of the device to make clear that the regulation applies only to the neurological uses of the device. The devices are:

Electroencephalogram (ECG) telemetry system (Docket No. 78N–1031).
Powered cranial compound drill, burr, trephine, and accessories (Docket No. 78N–1050).
Powered cranial simple drill, burr, trephine and accessories (Docket No. 78N–1051).
Cranial drill handpiece (brace) (Docket No. 78N–1052).
Electric cranial drill motor (Docket No. 78N–1053.
Pneumatic cranial drill motor (Docket No. 78N–1054).
Self-retaining neurosurgical retractor (Docket No. 78N–1070).
Implanted malleable clip (Docket No. 78N–1081).

These changes should eliminate some of the ambiguity that prompted the comments.

3. A comment stated that FDA should offer a second comment period if the original proposal is substantially altered in response to comments, e.g., if the final regulation places a device in a classification category that differs from the proposed classification.

In the case of any proposed classification regulation in which FDA makes substantial changes in response to comments, FDA will consider whether a reproposal is legally required, or is desirable as a matter of policy. The agency declines to commit itself to publishing a reproposal each time the classification category into which a device is placed differs from the proposed classification. The agency will evaluate each case on its own merits. Interested persons may also petition for reclassification of a device under Subpart C of Part 860 (21 CFR Part 860), the classification procedures regulation. In view of the availablility of the reclassification process, in most cases it would be an unnecessary procedural step to republish a proposed classification regulation merely because the device in the final regulation is in a classification different from that proposed.

4. A comment expressed concern over the completeness of the list of devices reviewed by the Neurological Device Classification Panel and for which classification proposals were published and noted that there was no mention of wound drainage devices. The comment also stated that because electrosurgical devices have an important role in neurosurgery, separate classification of electrosurgical devices by the Neurological Device Classification Panel may be warranted.

This is a valid point. There may well be devices on the market that FDA is unaware of and that should have been reviewed by the Panel but were not. As these devices come to FDA's attention, the agency will refer them to the Panel for classification recommendations and publish proposed classification regulations. It should be noted, however, that many devices used in the neurological field also are used in other medical specialities. The agency will publish proposed classification regulations for many such devices later. For example, devices for wound drainage and electrosurgery are used in several surgical specialties besides neurosurgery. When the agency publishes the recommendations of the General and Plastic Surgery Device Classification Panel and a proposed classification regulation for each of these devices, the recommendations of all panels that reviewed these devices will be included. FDA realizes that the use of electrosurgical devices in neurosurgery may be somewhat different from their use in other medical specialties because of the critical and delicate nature of neurosurgery. However, FDA does not believe that the differences are sufficient to warrant separate classification.

5. A comment suggested that reusable devices (e.g., surgical instruments) that come into contact with the central nervous system be classified into class III (premarket approval), because certain viruses can be transmitted from one patient to another if the devices are not adequately sterilized between uses. The comment also suggested that implantable devices should not be reused except, perhaps, for expensive electronic neuroprostheses, for which change of the outer coating material might be made mandatory for reuse.

FDA rejects the comment. Reusable devices, such as surgical instruments, should be capable of being sterilized by the user following each use. FDA can require by general controls or standards that manufacturers assure that they are. However, it is the responsibility of the users of the devices to assure that the devices are properly sterilized before reuse, and requiring premarket approval of reuseable devices would do nothing to assure that users carry out this responsibility. With respect to implantable devices, the agency agrees that implantable devices should not be reused except in very limited circumstances. FDA is unaware of any implantable neurological device that is being marketed as reuseable. Therefore, the agency is not changing the proposed classification category for any implantable neurological device. In the future, if a manufacturer desires to market an implantable neurological device that can be reused, FDA may require that it undergo premarket approval before it is marketed.

6. A comment pointed out that FDA proposed to classify 66 neurological devices into class II (performance standards) and questioned whether standards could be generated for so many devices in a reasonable period of time.

FDA agrees that it would be difficult to promulgate individual performance

standards for 66 neurological devices in the near future. However, the agency believes that the length of time required to develop a performance standard should not prevent a device that meets the criteria for class II from being classified into this category. Classification of the device into class II signals FDA's intention eventually to promulgate standards for the device. Until the standards are promulgated for a class II device, FDA has the same degree of regulatory control over the device as it does over a class I device. Futhermore, an individual performance standard will not be necessary for each device classified into class II. For example, some devices are being classified into class II only because of concerns about electrical safety. FDA may adopt a single electrical safety standard that would apply to many devices that present such concerns. In addition, to reduce the risks presented by certain class II devices, FDA is exploring the possibility of using voluntary standards, rather than mandatory standards under section 514 of the act (21 U.S.C. 360d).

7. A comment said that FDA should consider the effect of the GMP regulation on the safety and effectiveness of devices before classifying devices in class II. The comment stated that FDA should identify, for each device to be classified in class II, the specific characteristics of the device that need to be controlled by standards because they cannot be controlled by good manufacturing practices or other general controls.

FDA agrees that the adequacy of good manufacturing practice or other general control requirements to control the safety and effectiveness of a device must be considered before classifying a device in class II. FDA attempted to do this in the case of each class II recommendation. The agency does not agree that the characteristics of a device that need to be controlled by a performance standard need to be identified in the proposal to classify the device in class II. The Panel recommendation and classification proposal advise interested persons of many of the device characteristics that a performance standard should address. However, the Panel did not, and could not, always identify all possible risks to health presented by a device. The law does not require FDA to identify specifically the risks to be controlled by a performance standard until FDA publishes a notice under section 514(c) of the act inviting interested persons to submit existing standards or offers to develop proposed standards. FDA may, for neurological devices classified in class II, identify additional risks to health, or device characteristics, that need to be addressed by performance standards in notices published under section 514(c).

List of Neurological Devices

The following is a list of neurological devices being classified in final regulations published elsewhere in this issue of **Federal Register**. The list shows the section in the Code of Federal Regulations under which the regulation classifying the device is being codified, the docket number of the classification regulation, and the classification of each device.

Subpart B—Neurological Diagnostic Devices

Section	Device	Docket No.	Class
882.1020	Rigidity analyzer	78N-1001	II
882.1030	Ataxiagraph	78N-1002	II
882.1200	Two-point discriminator	78N-1003	I
882.1240	Echoencephalograph	78N-1004	II
882.1275	Electroconductive media	78N-1005	II
882.1310	Cortical electrode	78N-1006	II
882.1320	Cutaneous electrode	78N-1007	II
882.1330	Depth electrode	78N-1008	II
882.1340	Nasopharyngeal electrode	78N-1009	II
882.1350	Needle electrode	78N-1010	II
882.1400	Electroencephalograph	78N-1011	II
882.1410	Electroencephalograph electrode/lead tester	78N-1012	II
882.1420	Electroencephalogram (EEG) signal spectrum analyzer	78N-1013	II
882.1430	Electroencephalograph test signal generator	78N-1014	II
882.1460	Nystagmograph	78N-1015	II
882.1480	Neurological endoscope	78N-1016	II
882.1500	Esthesiometer	78N-1017	I
882.1525	Tuning fork	78N-1018	I
882.1540	Galvanic skin response measurement device	78N-1019	II
882.1550	Nerve conduction velocity measurement device	78N-1020	II
882.1560	Skin potential measurement device	78N-1021	II
882.1570	Powered direct-contact temperature measurement device	78N-1022	II
882.1610	Alpha monitor	78N-1023	II
882.1620	Intracranial pressure monitoring device	78N-1024	II
882.1700	Percussor	78N-1025	I
882.1750	Pinwheel	78N-1026	I
882.1790	Ocular plethysmograph	78N-1027	III
882.1825	Rheoencephalograph	78N-1028	III
882.1835	Physiological signal amplifier	78N-1029	II
882.1945	Physiological signal conditioner	78N-1030	II
882.1855	Electroencephalogram (EEG) telemetry system	78N-1031	II
882.1870	Evoked response electrical stimulator	78N-1032	II
882.1880	Evoked response mechanical stimulator	78N-1033	II
882.1890	Evoked response photic stimulator	78N-1034	II
882.1900	Evoked response auditory stimulator	78N-1035	II
882.1925	Ultrasonic scanner calibration test block	78N-1036	I
882.1950	Tremor transducer	78N-1037	II

Subparts C-D [Reserved]

Subpart E—Neurological Surgical Devices

Section	Device	Docket No.	Class
882.4030	Skull plate anvil	78N-1038	I
882.4060	Ventricular cannula	78N-1039	I
882.4100	Ventricular catheter	78N-1040	II
882.4125	Neurosurgical chair	78N-1041	I
882.4150	Scalp clip	78N-1042	II
882.4175	Aneurysm clip applier	78N-1043	II
882.4190	Clip forming/cutting instrument	78N-1044	I
882.4200	Clip removal instrument	78N-1045	I
882.4215	Clip rack	78N-1046	I

Section	Device	Docket No.	Class
882.4250	Cryogenic surgical device	78N-1047	II
882.4275	Dowel cutting instrument	78N-1048	II
882.4300	Manual cranial drill, burr, trephine, and accessories	78N-1049	II
882.4305	Powered compound cranial drill, burr, trephine, and accessories.	78N-1050	II
882.4310	Powered simple cranial drill, burr, trephine, and accessories	78N-1051	II
882.4325	Cranial drill handpiece (brace)	78N-1052	II
882.4360	Electric cranial drill motor	78N-1053	II
882.4370	Pneumatic cranial drill motor	78N-1054	II
882.4400	Radiofrequency lesion generator	78N-1055	II
882.4440	Neurosurgical headrest	78N-1057	I
882.4460	Neurosurgical head holder (skull clamp)	78N-1058	II
882.4500	Cranioplasty material forming instrument	78N-1059	I
882.4525	Microsurgical instrument	78N-1061	I
882.4535	Nonpowered neurosurgical instrument	78N-1062	I
882.4545	Shunt system implantation instrument	78N-1063	I
882.4560	Stereotaxic instrument	78N-1064	II
882.4600	Leukotome	78N-1065	I
882.4650	Neurosurgical suture needle	78N-1066	I
882.4700	Cottonoid paddie	78N-1067	II
882.4725	Radiofrequency lesion probe	78N-1068	II
882.4750	Skull punch	78N-1069	I
882.4800	Self-retaining retractor for neurosurgery	78N-1070	II
882.4840	Manual rongeur	78N-1071	II
882.4845	Powered rongeur	78N-1072	II
882.4900	Skullplate screwdriver	78N-1073	I

Subpart F—Neurological Therapeutic Devices

Section	Device	Docket No.	Class
882.5030	Methyl methacrylate for aneurysmorrhaphy	78N-1075	II
882.5050	Biofeedback device	78N-1076	II
882.5070	Bite block	78N-1077	II
882.5150	Intravascular occluding catheter	78N-1078	III
882.5175	Carotid artery clamp	78N-1079	II
882.5200	Aneurysm clip	78N-1080	II
882.5225	Implanted malleable clip	78N-1081	II
882.5235	Aversive conditioning device	78N-1082	II
882.5250	Burr hole cover	78N-1083	II
882.5275	Nerve cuff	78N-1084	II
882.5300	Methyl methacrylate for cranioplasty	78N-1085	II
882.5320	Preformed alterable cranioplasty plate	78N-1086	II
882.5330	Preformed nonalterable cranioplasty plate	78N-1087	II
882.5360	Cranioplasty plate fastener	78N-1088	II
882.5500	Lesion temperature monitor	78N-1089	II
882.5550	Central nervous system fluid shunt and components	78N-1090	II
882.5800	Cranial electrotherapy stimulator	78N-1091	III
882.5810	External functional neuromuscular stimulator	78N-1092	II
882.5820	Implanted cerebellar stimulator	78N-1093	III
882.5830	Implanted diaphragmatic/phrenic nerve stimulator	78N-1094	III
882.5840	Implanted intracerebral/subcortical stimulator for pain relief	78N-1095	III
882.5850	Implanted spinal cord stimulator for bladder evacuation	78N-1096	III
882.5860	Implanted neuromuscular stimulator	78N-1097	III
882.5870	Implanted peripheral nerve stimulator for pain relief	78N-1098	II
882.5880	Implanted spinal cord stimulator for pain relief	78N-1099	II
882.5890	Transcutaneous electrical nerve stimulator for pain relief	78N-1100	II
882.5900	Preformed craniosynostosis strip	78N-1101	II
882.5910	Dura substitute	78N-1102	II
882.5940	Electroconvulsive therapy device	78N-1103	III
882.5950	Artificial embolization device	78N-1104	III
882.5960	Skull tong for traction	78N-1105	II

Patient Information

FDA is considering requiring the development and dissemination of information for patients and consumers about the uses, benefits, and risks of medical devices. For example, patient information has already been required or approved by FDA for intrauterine devices and hearing aids. In addition, the Bureau of Radiological Health is conducting a consumer education program on x-rays that includes posters on the effects of radiation during pregnancy and the distribution of x-ray record cards.

FDA believes that patient information is needed if: (1) There is a choice among alternatives of which the patient should be aware; (2) There are substantial risks or discomforts associated with the product; (3) The cost of the product is significant; (4) There is a need for the patient to strictly adhere to a specific treatment regimen; and (5) There is substantial public or professional controversy about the device or its related procedures.

FDA can require that manufacturers make medical device information available to providers for their use and the use of their patients through the premarket approval or standards setting processes as well as the general control provisions of the Federal Food, Drug, and Cosmetic Act. The mechanisms available to FDA to provide patient information for devices include: (1) Labeling for restricted and nonrestricted devices; (2) Patient package inserts and provider information; and (3) Consumer and patient education programs.

FDA has tentatively identified several neurological devices for which patient information may be required. Other neurological devices may be identified in the future, after the criteria for selection of devices needing patient information have been further refined. The devices that have been identified so far are listed below:

Device	Docket No.
Central nervous system fluid shunts and components	78N-1090
External functional neuromuscular stimulator	78N-1092
Implanted cerebellar stimulator	78N-1093
Implanted diaphragmatic/phrenic nerve stimulator	78N-1094
Implanted intracerebral/subcortical stimulator for pain relief	78N-1095
Implanted spinal cord stimulator for bladder evacuation	78N-1096
Implanted neruromuscular stimulator	78N-1097
implanted peripheral nerve stimulator for pain relief	78N-1098
Implanted spinal cord stimulator for pain relief	78N-1099
Electroconvulsive therapy device	78N-1103

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs amends Chapter I of Title 21 of the Code of Federal Regulations by adding new Part 882, Subpart A, to read as follows:

PART 882—NEUROLOGICAL DEVICES

Subpart A—General Provisions

Sec.

882.1 Scope.

Authority: Secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360C, 701(a)).

Subpart A—General Provisions

§ 882.1 Scope.

(a) This part sets forth the classification of neurological devices intended for human use.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 of this chapter may not show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87 of this chapter.

(c) To avoid duplicative listings, a neurological device that has two or more types of uses (e.g., use both as a diagnostic device and as a therapeutic device) is listed in the subpart representing one use of the device, rather than in two or more subparts.

Effective date. This regulation is effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26791 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1001]

Neurological Devices; Classification of Rigidity Analyzers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying rigidity analyzers into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55645) a proposed regulation to classify rigidity analyzers into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 by adding Subpart B and § 882.1020, to read as follows:

Subpart B—Neurological Diagnostic Devices

§ 882.1020 Rigidity analyzer.

(a) *Identification.* A rigidity analyzer is a device for quantifying the extent of the rigidity of a patient's limb to determine the effectiveness of drugs or other treatments.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26792 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1002]

Neurological Devices; Classification of Ataxiagraphs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying ataxiagraphs into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55646) a proposed regulation to classify ataxiagraphs into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1030, to read as follows:

§ 882.1030 Ataxiagraph.

(a) *Identification.* An ataxiagraph is a device to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26793 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1003]

Neurological Devices; Classification of Two-Point Discriminators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying two-point discriminators into class I (general controls) and exempting manufacturers of the device from the good manufacturing practice regulation. The effect of this rule is to require that the device meet only the general controls applicable to all devices, except for the good manufacturing practice regulation. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55646) a proposed regulation to classify two-point discriminators into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. FDA proposed that this device be exempt from the good manufacturing practice (GMP) requirements in Part 820 (21 CFR Part 820), including the recordkeeping and reporting requirements in Part 820. FDA has determined that exemption of devices from the GMP requirements should not extend to § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, or § 820.198 (21 CFR 820.198), with respect to complaint files. The agency believes that granting exemptions from these sections would not be in the public interest, and that compliance with these sections is not unduly burdensome for device manufacturers. FDA is, however, exempting the device from all other sections of the GMP regulations. Accordingly, the proposed rule is being adopted with these changes.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1200, to read as follows:

§ 882.1200 Two-point discriminator.

(a) *Identification.* A two-point discriminator is a device with points used for testing a patient's touch discrimination.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26794 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1004]

Neurological Devices; Classification of Echoencephalographs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying echoencephalographs into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55647) a proposed regulation to classify echoencephalographs into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1240, to read as follows:

§ 882.1240 Echoencephalograph.

(a) *Identification.* An echoencephalograph is an ultrasonic scanning device (including A-scan, B-scan, and doppler systems) that uses noninvasive transducers for measuring intracranial interfaces and blood flow velocity to and in the head.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26795 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1005]

Neurological Devices; Classification of Electroconductive Media

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying electroconductive media into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55648) a proposed regulation to classify electroconductive media into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1275, to read as follows:

§ 882.1275 Electroconductive media.

(a) *Identification.* Electroconductive media are the conductive creams or gels used with external electrodes to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26796 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1006]

Neurological Devices; Classification of Cortical Electrodes

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying cortical electrodes into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55649) a proposed regulation to classify cortical electrodes into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

Two comments were received. The comments suggested that any invasive device (e.g., cortical electrodes) may be capable of transmitting from patient to patient viral diseases of the central nervous system if the device is reuseable. One of the comments suggested that these devices be classified into class III (premarket approval) because of this risk.

The agency believes that the risk of transmitting central nervous system diseases from patient to patient by cortical electrodes can be avoided by requiring in a performance standard that cortical electrodes either be disposable (single-use only) or capable of being repeatedly sterilized by the user. Therefore, the agency rejects the comment to classify cortical electrodes in class III. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1310, to read as follows:

§ 882.1310 Cortical electrode.

(a) *Identification.* A cortical electrode is an electrode which is temporarily placed on the surface of the brain for stimulating the brain or recording the brain's electrical activity.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26797 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1007]

Neurological Devices; Classification of Cutaneous Electrodes

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying cutaneous electrodes into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a

proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55650) a proposed regulation to classify cutaneous electrodes into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No comments were received that objected to classifying cutaneous electrodes into class II. However, one comment pointed out that electrodes that come into contact with abraded skin or blood (e.g., cutaneous electrodes) may transmit viral diseases and should therefore be capable of being sterilized.

As was stated in the preamble to the proposed general provisions for neurological devices (43 FR 55640), the agency recognizes that all possible risks to health presented by neurological devices may not have been identified in the classification recommendations and the proposed FDA regulations. Future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) may identify other risks to health that are to be addressed by FDA requirements in addition to those identified in the classification recommendations and regulations. The risk of transmitting viral diseases because of electrodes that are not sterile will be considered along with other risks to health presented by cutaneous electrodes when the agency proposes to establish performance standards for cutaneous electrodes. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1320, to read as follows:

§ 882.1320 Cutaneous electrode.

(a) *Identification.* A cutaneous electrode is an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26798 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1008]

Neurological Devices; Classification of Depth Electrodes

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying depth electrodes into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55650) a proposed regulation to classify depth electrodes into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

Two comments suggested that a depth electrode may be capable of transmitting from patient to patient viral diseases of the central nervous system if the device is reuseable. One of the comments suggested that depth electrodes be classified into class III (premarket approval) because of this risk.

The agency believes that the risk of transmitting central nervous system diseases from patient to patient by depth electrodes can be avoided by requiring in a performance standard that depth electrodes be either disposable (single-use only) or capable of being repeatedly sterilized by the user. Therefore, the agency rejects the comment to classify depth electrodes in class III. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1330, to read as follows:

§ 882.1330 Depth electrode.

(a) *Identification.* A depth electrode is an electrode used for temporary stimulation of, or recording electrical signals at, subsurface levels of the brain.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26799 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1009]

Neurological Devices; Classification of Nasopharyngeal Electrodes

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying nasopharyngeal electrodes into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations

classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55651) a proposed regulation to classify nasopharyngeal electrodes into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No comments were received that objected to classifying nasopharyngeal electrodes into class II. However, one comment pointed out that electrodes that come into contact with abraded skin or blood (e.g., nasopharyngeal electrodes) may transmit viral disease and should therefore be capable of being sterilized.

As was stated in the preamble to the proposed general provisions for neurological devices (43 FR 55640), the agency recognizes that all possible risks to health presented by neurological devices may not have been identified in the classification recommendation and the proposed FDA regulations. Future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) may identify other risks to health that are to be addressed by FDA requirements in addition to those identified in the classification recommendations and regulations. The risk of transmitting viral diseases because of electrodes that are not sterile will be considered along with other risks to health presented by nasopharyngeal electrodes when the agency proposes to establish performance standards for nasopharyngeal electrodes. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1340, to read as follows:

§ 882.1340 Nasopharyngeal electrode.

(a) *Identification.* A nasopharyngeal electrode is an electrode which is temporarily placed in the nasopharyngeal region for the purpose of recording electrical activity.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26800 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1010]

Neurological Devices; Classification of Needle Electrodes

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying needle electrodes into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55652) a proposed regulation to classify needle electrodes into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

Two comments suggested that a needle electrode may be capable of transmitting from patient to patient viral diseases of the central nervous system if the device is reuseable. One of the comments suggested that needle electrodes be classified into class III (premarket approval) because of this risk.

The agency believes that the risk of transmitting central nervous system diseases from patient to patient by needle electrodes can be avoided by requiring in a performance standard that needle electrodes be either disposable (single-use only) or capable of being repeatedly sterilized by the user. Therefore, the agency rejects the comment to classify needle electrodes in class III. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1350, to read as follows:

§ 882.1350 Needle electrode.

(a) *Identification.* A needle electrode is a device which is placed subcutaneously to stimulate or to record electrical signals.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26801 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1011]

Neurological Devices; Classification of Electroencephalographs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying electroencephalographs into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations

classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55653) a proposed regulation to classify electroencephalographs into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1400, to read as follows:

§ 882.1400 Electroencephalograph.

(a) *Identification.* An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26802 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1012]

Neurological Devices; Classification of Electroencephalograph Electrode/Lead Testers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying electroencephalograph electrode/lead testers into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55653) a proposed regulation to classify electroencephalograph electrode/lead testers into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1410, to read as follows:

§ 882.1410 Electroencephalograph electrode/lead tester.

(a) *Identification.* An electroencephalograph electrode/lead tester is a device used for testing the impedance (resistance to alternating current) of the electrode and lead system of an electroencephalograph to assure that an adequate contact is made between the electrode and the skin.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26803 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1013]

Neurological Devices; Classification of Electroencephalogram (EEG) Signal Spectrum Analyzers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying electroencephalogram (EEG) signal spectrum analyzers into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55654) a proposed regulation to classify electroencephalogram (EEG) signal spectrum analyzers into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1420, to read as follows:

§ 882.1420 Electroencephalogram (EEG) signal spectrum analyzer.

(a) *Identification.* An electroencephalogram (EEG) signal spectrum analyzer is a device used to display the frequency content or power

spectral density of the electroencephalogram (EEG) signal.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26804 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1014]

Neurological Devices; Classification of Electroencephalograph Test Signal Generators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying electroencephalograph test signal generators into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55655) a proposed regulation to classify electroencephalograph test signal generators into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1430, to read as follows:

§ 882.1430 Electroencephalograph test signal generator.

(a) *Identification.* An electroencephalograph test signal generator is a device used to test or calibrate an electroencephalograph.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26805 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1015]

Neurological Devices; Classification of Nystagmographs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying nystagmographs into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55655) a proposed regulation to classify nystagmographs into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1460, to read as follows:

§ 882.1460 Nystagmograph.

(a) *Identification.* A nystagmograph is a device used to measure, record, or visually display the involuntary movements (nystagmus) of the eyeball.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26806 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1016]

Neurological Devices; Classification of Neurological Endoscopes

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying neurological endoscopes into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia

Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55656) a proposed regulation to classify neurological endoscopes into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1480, to read as follows:

§ 882.1480 Neurological endoscope.

(a) *Identification.* A neurological endoscope is an instrument with a light source used to view the inside of the ventricles of the brain.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26807 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1017]

Neurological Devices; Classification of Esthesiometers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying esthesiometers into class I (general controls) and exempting manufacturers of the device from the good manufacturing practice regulation. The effect of this rule is to require that the device meet only the general controls applicable to all devices, except for the good manufacturing practice regulation. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55657) a proposed regulation to classify esthesiometers into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. FDA proposed that this device be exempt from the good manufacturing practice (GMP) requirements in Part 820 (21 CFR Part 820), including the recordkeeping and reporting requirements in Part 820. FDA has determined that exemption of devices from the GMP requirements should not extend to § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, or § 820.198 (21 CFR 820.198), with respect to complaint files. The agency believes that granting exemptions from these sections would not be in the public interest, and that compliance with these sections is not unduly burdensome for device manufacturers. FDA is, however, exempting the device from all other sections of the GMP regulations. Accordingly, the proposed rule is being adopted with these changes.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1500, to read as follows:

§ 882.1500 Esthesiometer.

(a) *Identification.* An esthesiometer is a mechanical device which usually consists of a single rod or fiber which is held in the fingers of the physician or other examiner and which is used to determine whether a patient has tactile sensitivity.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26808 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1018]

Neurological Devices; Classification of Tuning Forks

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying tuning forks into class I (general controls) and exempting manufacturers of the device from the good manufacturing practice regulation. The effect of this rule is to require that the device meet only the general controls applicable to all devices, except for the good manufacturing practice regulation. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55658) a proposed regulation to classify tuning forks into class I (general controls). A

period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. FDA proposed that this device be exempt from the good manufacturing practice (GMP) requirements in Part 820 (21 CFR Part 820), including the recordkeeping and reporting requirements in Part 820. FDA has determined that exemption of devices from the GMP requirements should not extend to § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, or § 820.198 (21 CFR 820.198), with respect to complaint files. The agency believes that granting exemptions from these sections would not be in the public interest, and that compliance with these sections is not unduly burdensome for device manufacturers. FDA is, however, exempting the device from all other sections of the GMP regulations. Accordingly, the proposed rule is being adopted with these changes.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1525, to read as follows:

§ 882.1525 Tuning fork.

(a) *Identification.* A tuning fork is a mechanical device which resonates at a given frequency and is used to diagnose hearing disorders and to test for vibratory sense.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26809 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1019]

Neurological Devices; Classification of Galvanic Skin Response Measurement Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying galvanic skin response measurement devices into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulation classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55658) a proposed regulation to classify galvanic skin response measurement devices into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1540, to read as follows:

§ 882.1540 Galvanic skin response measurement device.

(a) *Identification.* A galvanic skin response measurement device is a device used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26810 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1020]

Neurological Devices; Classification of Nerve Conduction Velocity Measurement Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying nerve conduction velocity measurement devices into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55659) a proposed regulation to classify nerve conduction velocity measurement devices into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device.

Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1550, to read as follows:

§ 882.1550 Nerve conduction velocity measurement device.

(a) *Identification.* A nerve conduction velocity measurement device is a device which measures nerve conduction time by applying a stimulus, usually to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26811 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1021]

Neurological Devices; Classification of Skin Potential Measurement Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying skin potential measurement devices into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55660) a proposed regulation to classify skin potential measurement devices into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1560, to read as follows:

§ 882.1560 Skin potential measurement device.

(a) *Identification.* A skin potential measurement device is a general diagnostic device used to measure skin voltage by means of surface skin electrodes.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26812 Filed 8-31-79; 8:45 am]

Billing Code 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1022]

Neurological Devices; Classification of Powered Direct-Contact Temperature Measurement Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying powered direct-contact temperature measurement devices into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55661) a proposed regulation to classify powered direct-contact temperature measurement devices into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1570, to read as follows:

§ 882.1570 Powered direct-contact temperature measurement device.

(a) *Identification.* A powered direct-contact temperature measurement device is a device which contains a power source and is used to measure differences in temperature between two points on the body.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26813 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1023]

Neurological Devices; Classification of Alpha Monitors

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying alpha monitors into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55662) a proposed regulation to classify alpha monitors into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1610, to read as follows:

§ 882.1610 Alpha monitor.

(a) *Identification.* An alpha monitor is a device with electrodes that are placed on a patient's scalp to monitor that portion of the electroencephalogram which is referred to as the alpha wave.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-28814 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1024]

Neurological Devices; Classification of Intracranial Pressure Monitoring Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying intracranial pressure monitoring devices into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55662) a proposed regulation to classify intracranial pressure monitoring devices into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

One comment suggested that any invasive device, such as an intracranial pressure (ICP) monitoring device, may be capable of transmitting from patient to patient viral diseases of the central nervous system if the device is reuseable. The comment suggested that these devices be classified into class III (premarket approval) because of this risk.

The agency believes that the risk of transmitting central nervous system disease from patient to patient by intracranial pressure monitoring devices can be avoided by requiring in a performance standard that intracranial pressure monitoring devices either be disposable (single-use only) or capable of being repeatedly sterilized by the user. Therefore, the agency rejects the comment to classify intracranial pressure monitoring devices in class III.

Another comment agreed with classifying intracranial pressure monitoring devices in class II but suggested that the development of a performance standard be a high priority for the devices instead of a low priority as proposed because of the increasing use of ICP monitoring and the proliferation of types of ICP monitoring devices.

On February 23, 1979, FDA referred this comment to the Neurological Section of the Respiratory and Nervous System Devices Panel (formerly the Neurological Device Classification Panel). The Panel agreed with the comment and recommended that the priority for development of performance standards for intracranial pressure monitoring devices be changed to "high." As was stated in the preamble to the proposed general provisions for neurological devices (43 FR 55640), the agency is not proposing at this time to establish priorities for development of performance standards for class II devices. At a later date, the agency will establish priorities for the development of performance standards for class II devices based on the classification panel's recommendations, available resources, and other relevant factors. Accordingly, the proposed regulation is being adopted as written.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1620, to read as follows:

§ 882.1620 Intracranial pressure monitoring device.

(a) *Identification.* An intracranial pressure monitoring device is a device used for short-term monitoring and recording of intracranial pressures and pressure trends. The devices includes the transducer, monitor, and interconnecting hardware.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26815 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1025]

Neurological Devices: Classification of Percussors

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying percussors into class I (general controls) and exempting manufacturers of the device from the good manufacturing practice regulation. The effect of this rule is to require that the device meet only the general controls applicable to all devices, except for the good manufacturing practice regulation. This action is being taken under the Medical Device Amendment of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55664) a proposed regulation to classify percussors into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. FDA proposed that this device be exempt from the good manufacturing practice (GMP) requirements in Part 820 (21 CFR Part 820) including the recordkeeping and reporting requirements in Part 820. FDA has determined that exemption of devices from the GMP requirements should not extend to § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, or § 820.198 (21 CFR 820.198), with respect to complaint files. The agency believes that granting exemptions from these sections would not be in the public interest, and that compliance with these sections is not unduly burdensome for device manufacturers. FDA is, however, exempting the device from all other sections of the GMP regulations. Accordingly, the proposed rule is being adopted with these changes.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1700, to read as follows:

§ 882.1700 Percussor.

(a) *Identification.* A percussor is a small hammerlike device used by a physician to provide light blows to a body part. A percussor is used as a diagnostic aid during physical examinations.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26816 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1026]

Neurological Devices; Classification of Pinwheels

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying pinwheels into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55664) a proposed regulation to classify pinwheels into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1750, to read as follows:

§ 882.1750 Pinwheel.

(a) *Identification.* A pinwheel is a device with sharp points on a rotating wheel used for testing pain sensation.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26817 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1027]

Neurological Devices; Classification of Ocular Plethysmographs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying ocular plethysmographs into class III (premarket approval). The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. Each application must be submitted to FDA on or before May 28, 1982, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55665) a proposed regulation to classify ocular plethysmographs into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

One comment was received. The comment disagreed with the reasons given for classifying ocular plethysmographs into class III. The comment asserted that the pneumoplethysmographic technique has been shown to be very effective in several recent studies and has a low incidence of complications. The comment also stated that the other techniques of ocular plethysmography are not as good as the pneumoplethysmographic technique, and that they may be difficult to apply and the results difficult to interpret. The comment also disagreed that carotid compression is a major hazard when using the pneumoplethysmographic technique because carotid compression is infrequently used and, when used, is safe if done by those experienced in its use.

FDA agrees that some of the ocular plethysmograph devices are more effective than others. The fact that a device is effective, however, is not a reason for classifying it in class I or II. As a group, ocular plethysmographs are devices that present a potential unreasonable risk of illness or injury to the patient. FDA concluded that there is insufficient information to establish a performance standard that would assure the safety and effectiveness of ocular plethysmographs and, for this reason, that the devices should be classified in class III. This conclusion does not preclude approval of a premarket approval application for a particular ocular plethysmograph device. Accordingly, the proposed rule is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1790, to read as follows:

§ 882.1790 Ocular plethysmograph.

(a) *Identification.* An ocular plethysmograph is a device used to measure or detect volume changes in the eye produced by pulsations of the artery, to diagnose carotid artery occlusive disease (restrictions on blood flow in the carotid artery).

(b) *Classification.* Class III (premarket approval).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26818 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1028]

Neurological Devices; Classification of Rheoencephalographs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying rheoencephalographs into class III (premarket approval). The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. Each application must be submitted to FDA on or before May 28, 1982 or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55666) a proposed regulation to classify rheoencephalographs into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1825, to read as follows:

§ 882.1825 Rheoencephalograph.

(a) *Identification.* A rheoencephalograph is a device used to estimate a patient's cerebral circulation (blood flow in the brain) by electrical inpedance methods with direct electrical connections to the scalp or neck area.

(b) *Classification.* Class III (premarket approval).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26819 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 882

[Docket No. 78N-1029]

Neurological Devices; Classification of Physiological Signal Amplifiers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying physiological signal amplifiers into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55667) a proposed regulation to classify physiological signal amplifiers into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1835, to read as follows:

§ 882.1835 Physiological signal amplifier.

(a) *Identification.* A physiological signal amplifier is a general purpose device used to electrically amplify signals derived from various physiological sources (e.g., the electroencephalogram).

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26820 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1030]

Neurological Devices; Classification of Physiological Signal Conditioners

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying physiological signal conditioners into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55668) a proposed regulation to classify physiological signal conditioners into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1845, to read as follows:

§ 882.1845 Physiological signal conditioner.

(a) *Identification.* A physiological signal conditioner is a device such as an integrator or differentiator used to modify physiological signals for recording and processing.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26821 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1031]

Neurological Devices: Classification of Electroencephalogram (EEG) Telemetry Systems

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying electroencephalogram (EEG) telemetry systems into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55668) a

proposed regulation to classify physiological signal telemetry systems into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

A comment agreed with the proposal to classify physiological signal telemetry systems into class II and pointed out the danger of inherent leakage currents that are present when telephone telemetry systems are used.

The agency agrees with the comment that electrical leakage current is a potential hazard of using telephone telemetry systems.

The agency has made minor changes to the name and identification of this device to make it clear that the rule applies to those devices used to transmit the electroencephalogram (EEG). Separate proposals have recently been published (44 FR 13358 and 13359; March 9, 1979) for telemetry transmitters and receivers used to transmit cardiovascular signals. Accordingly, the proposed regulation is being adopted with these changes.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1855, to read as follows:

§ 882.1855 Electroencephalogram (EEG) telemetry system.

(a) *Identification.* An electroencephalogram (EEG) telemetry system consists of transmitters, receivers, and other components used for remotely monitoring or measuring EEG signals by means of radio or telephone transmission systems.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26822 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1032]

Neurological Devices; Classification of Evoked Response Electrical Stimulators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying evoked response electrical stimulators into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55669) a proposed regulation to classify evoked response electrical stimulators into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1870, to read as follows:

§ 882.1870 Evoked response electrical stimulator.

(a) *Identification.* An evoked response electrical stimulator is a device used to apply an electrical stimulus to a patient by means of skin electrodes for the purpose of measuring the evoked response.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26823 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1033]

Neurological Devices: Classification of Evoked Response Mechanical Stimulators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying evoked response mechanical stimulators into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55670) a proposed regulation to classify evoked response mechanical stimulators into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1880, to read as follows:

§ 882.1880 Evoked response mechanical stimulator.

(a) *Identification.* An evoked response mechanical stimulator is a device used to produce a mechanical stimulus or a series of mechanical stimuli for the purpose of measuring a patient's evoked response.

(b) *Classification.* Class II (performance standards).

Effective date. This regulaton shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26824 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1034]

Neurological Devices; Classification of Evoked Response Photic Stimulators

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying evoked response photic stimulators into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55671) a proposed regulation to classify evoked response photic stimulators into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

A comment pointed out that the identification for evoked response photic stimulators did not include the so-called "pattern-shift generator" that presents to the patient a shifting pattern on a television screen. The comment also pointed out that the pattern-shift generators used in evoked response measurements could be hazardous because the shifting pattern might evoke an epileptic seizure in some epileptic patients.

The agency agrees that minor changes should be made in the language used in the identification of the evoked response photic stimulator to make it clear that it includes the pattern-shift devices. The agency acknowledges the health hazard identified in the comment. Accordingly, the proposed regulation is adopted with the changes noted.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1890, to read as follows:

§ 882.1890 Evoked response photic stimulator.

(a) *Identification.* An evoked response photic stimulator is a device used to generate and display a shifting pattern or to apply a brief light stimulus to a patient's eye for use in evoked response measurements or for electroencephalogram (EEG) activation.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26825 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1035]

Neurological Devices; Classification of Evoked Response Auditory Stimulators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying evoked response auditory stimulators into class II (performance standards). The effect of classifying a device into Class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55672) a proposed regulation to classify evoked response auditory stimulators into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1900, to read as follows:

§ 882.1900 Evoked response auditory stimulator.

(a) *Identification.* An evoked response auditory stimulator is a device that produces a sound stimulus for use in evoked response measurements or electroencephalogram activation.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26826 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1036]

Neurological Devices; Classification of Ultrasonic Scanner Calibration Test Blocks

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying ultrasonic scanner calibration test blocks into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55672) a proposed regulation to classify ultrasonic scanner calibration test blocks into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adoped without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1925, to read as follows:

§ 882.1925 Ultrasonic scanner calibration test block.

(a) *Identification.* An ultrasonic scanner calibration test block is a block of material with known properties used to calibrate ultrasonic scanning devices (e.g., the echoencephalograph).

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26827 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1037]

Neurological Devices; Classification of Tremor Transducers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying tremor transducers into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55673) a proposed regulation to classify tremor transducers into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart B by adding new § 882.1950, to read as follows:

§ 882.1950 Tremor transducer.

(a) *Identification.* A tremor transducer is a device used to measure the degree of tremor caused by certain diseases.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26828 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1038]

Neurological Devices; Classification of Skull Plate Anvils

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying skull plate anvils into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55674) a proposed regulation to classify skull plate anvils into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed

regulation to classifying this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 by adding new Subpart E and § 882.4030, to read as follows:

Subparts C and D—[Reserved]

Subpart E—Neurological Surgical Devices

§ 882.4030 Skull plate anvil.

(a) *Identification.* A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of a patient's skull.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26829 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1039]

Neurological Devices; Classification of Ventricular Cannulas

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying ventricular cannulas into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55674) a proposed regulation to classify ventricular cannulas into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4060, to read as follows:

§ 882.4060 Ventricular cannula.

(a) *Identification.* A ventricular cannula is a device used to puncture the ventricles of the brain for aspiration or for injection. This device is frequently referred to as a ventricular needle.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26830 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1040]

Neurological Devices; Classification of Ventricular Catheters

AGENCY: The Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying ventricular catheters into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55675) a proposed regulation to classify ventricular catheters into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

One comment was received. The comment suggested that the ventricular catheter be classified into class I because the risks to health identified for the device are the same as those identified for the ventricular cannula, which the agency proposed to classify in class I (43 FR 55674). The comment noted that the only explanation for the difference in the classification of the two devices was that the ventricular catheter may be left in the patient longer than the venticular cannula.

The agency disagrees with the comment. The agency proposed that the ventricular catheter and the ventricular cannula be classified in different classes because the characteristics of the devices that present risks to the patient are different and they require different levels of control. For instance, metal ventricular cannulas can be adequately controlled by general controls because it is relatively easy for the user to determine by inspection if the device has design or construction flaws. However, the user cannot easily determine by inspection whether a flexible catheter constructed of a polymeric substance may deteriorate while in use. The agency believes that a standard that controls the type of material used in the ventricular catheter and the performance of the device is necessary to provide reasonable assurance that the device will function properly without unnecessary risk to the patient. Accordingly, the proposed rule is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the

Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4100, to read as follows:

§ 882.4100 Ventricular catheter.

(a) *Identification.* A ventricular catheter is a device used to gain access to the cavities of the brain for injection of material into, or removal of material from, the brain.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26831 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1041]

Neurological Devices; Classification of Neurosurgical Chairs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying neurosurgical chairs into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55676) a proposed regulation to classify neurosurgical chairs into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4125, to read as follows:

§ 882.4125 Neurosurgical chair.

(a) *Identification.* A neurosurgical chair is an operating room chair used to position and support a patient during neurosurgery.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26832 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1042]

Neurological Devices; Classification of Scalp Clips

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying scalp clips into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55676) a proposed regulation to classify scalp clips into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

A comment suggested that the class of devices known as wound clips not be required to meet standards, as proposed for scalp clips. The comment noted that the pressure exerted by a wound clip is entirely under the control of the surgeon, and, therefore, the manufacturer cannot assure that the pressure that the clip applies to tissue is appropriate. The comment also suggested that separate standards should not be developed for wound clips and scalp clips if possible because separate standards may result in confusion, mutually exclusive requirements, and possible monetary waste.

The agency has considered publishing one regulation that would apply to both scalp clips and wound clips. However, the agency believes that devices known as scalp clips are different enough from wound clips so that a separate classification regulation is needed. A proposed classification regulation applicable to wound clips will be published separately later. The comment does not deal with scalp clips. Accordingly, the proposed regulation for scalp clips is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4150, to read as follows:

§ 882.4150 Scalp clip.

(a) *Identification.* A scalp clip is a plastic or metal clip used to stop bleeding during surgery on the scalp.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26833 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1043]

Neurological Devices; Classification of Aneurysm Clip Appliers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying aneurysm clip appliers into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55677) a proposed regulation to classify aneurysm clip appliers into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4175, to read as follows:

§ 882.4175 Aneurysm clip applier.

(a) *Identification.* An aneurysm clip applier is a device used by the surgeon for holding and applying intracranial aneurysm clips.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26834 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1044]

Neurological Devices; Classification of Clip Forming/Cutting Instruments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying clip forming/cutting instruments into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55678) a proposed regulation to classify clip forming/cutting instruments into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4190, to read as follows:

§ 882.4190 Clip forming/cutting instrument.

(a) *Identification.* A clip forming/cutting instrument is a device used by the physician to make tissue clips from wire stock.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26835 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1045]

Neurological Devices; Classification of Clip Removal Instruments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying clip removal instruments into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55678) a proposed regulation to classify clip removal instruments into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed

regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4200, to read as follows:

§ 882.4200 Clip removal instrument.

(a) *Identification.* A clip removal instrument is a device used to remove surgical clips from the patient.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26836 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1046]

Neurological Devices; Classification of Clip Racks

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying clip racks into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55679) a proposed regulation to classify clip racks into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4215, to read as follows:

§ 882.4215 Clip rack.

(a) *Identification.* A clip rack is a device used to hold or store surgical clips during surgery.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26837 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1047]

Neurological Devices; Classification of Cryogenic Surgical Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying cryogenic surgical devices into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55680) a proposed regulation to classify cryogenic surgical devices into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4250, to read as follows:

§ 882.4250 Cryogenic surgical device.

(a) *Identification.* A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in nervous tissue by the application of extreme cold to the selected site.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26838 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1048]

Neurological Devices; Classification of Dowel Cutting Instruments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying dowel cutting instruments into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the

safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55680) a proposed regulation to classify dowel cutting instruments into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

One comment was received. The comment disagreed with the proposal to classify dowel cutting instruments into class I and suggested that the device be classified into class II instead. The comment noted that the cutting teeth on the device may lacerate pelvic muscle and cause hemorrhage if the device uncontrollably plunges through the inner table of the bone and strikes pelvic structures. A performance standard should address the risk of uncontrollable plunging of the device and the means used by the instrument to control the bone dowel after it has been cut so that it may be retrieved easily.

FDA agrees with the comment. On February 23, 1979, the Neurological Section of the Respiratory and Nervous Systems Devices Panel (formerly the Neurological Device Classification Panel) reviewed the comment and recommended that FDA classify dowel cutting instruments into class II because the hazards identified by the comment cannot be adequately controlled by general controls.

FDA agrees with the Panel and is changing the classification of dowel cutting instruments from class I to class II in the final rule. For the reasons stated in the general regulation on neurological devices, published elsewhere in this issue of the **Federal Register**, FDA does not believe that it is necessary to issue a new proposal concerning this decision. Persons who disagree with classifying dowel cutting instruments in class II may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860), the classification procedures regulation.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4275, to read as follows:

§ 882.4275 Dowel cutting instrument.

(a) *Identification.* A dowel cutting instrument is a device used to cut dowels of bone for bone grafting.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26839 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1049]

Neurological Devices; Classification of Manual Cranial Drills, Burrs, Trephines, and Their Accessories

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying manual cranial drills burrs, trephines, and their accessories into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55681) a proposed regulation to classify manual drills, burrs, trephines, and their accessories into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

A comment objected to classifying manual drills, burrs, trephines, and their accessories into class II and suggested that these devices be classified instead into class I (general controls) because the devices are hand operated and the manufacturer has no way of controlling whether they are properly used. The comment also stated that there are now in effect for these devices standards that were developed by the International Standards Organization (ISO), and more meaningful standards cannot be established without a great deal of expense.

The agency agrees with the comment that the manufacturers cannot always prevent the device from being misused. However, the agency does not agree with and will not adopt the comment's recommendation that the device be classified into class I. The Neurological Device Classification Panel recommended that manual drills, burrs, trephines, and their accessories be classifed into class II to require the devices to have guards that will prevent the device tips from plunging into the patient's brain. The agency agrees with the panel that a performance standard is necessary for this device. The agency is unaware of any existing standards for this device that require guards to prevent the tips of the device from plunging into the patient's brain. However, the agency believes that several organizations have formed committees to work on standards that may apply to this device. If a standard that applies to this device is developed in the future, the agency will consider adopting it rather than developing a separate FDA standard.

The agency has made minor changes to the name and identification of the device to make it clear that the rule applies to those devices that are used on a patient's skull. Separate proposed regulations will be issued later for other types of manual drills and accessories (e.g., dental). Accordingly, the proposed regulation is being adopted with these changes.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by

adding new § 882.4300, to read as follows:

§ 882.4300 Manual cranial drills, burrs, trephines, and their accessories

(a) *Identification.* Manual cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments that are used without a power source on a patient's skull.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26840 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1050]

Neurological Devices; Classification of Powered Compound Cranial Drills, Burrs, Trephines, and Their Accessories

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying powered compound cranial drills, burrs, trephines, and their accessories into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55682) a proposed regulation to classify powered compound drills, burrs, trephines, and their accessories into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. However, the agency has made minor changes to the name and identification of the device to make it clear that the rule applies to those devices that are used on a patient's skull. Separate proposed regulations will be issued later for other types of compound drills and accessories (e.g., dental). Accordingly, the proposed regulation is being adopted with these changes.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4305, to read as follows:

§ 882.4305 Powered compound cranial drills, burrs, trephines, and their accessories.

(a) *Identification.* Powered compound cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used on a patient's skull. The instruments employ a clutch mechanism to disengage the tip of the instrument after penetrating the skull to prevent plunging of the tip into the brain.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26841 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1051]

Neurological Devices; Classification of Powered Simple Cranial Drills, Burrs, Trephines, and Their Accessories

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying powered simple cranial drills, burrs, trephines, and their accessories into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55682) a proposed regulation to classify powered simple drills, burrs, trephines, and their accessories into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. However, the agency has made minor changes to the name and identification of the device to make it clear that the rule applies to those devices that are used on a patient's skull. Separate proposed regulations will be issued later for other types of simple drills and accessories (e.g., dental). Accordingly, the proposed regulation is being adopted with these changes.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4310, to read as follows:

§ 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories.

(a) *Identification.* Powered simple cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used on a patient's skull. The instruments are used with a power source but do not have a clutch mechanism to disengage the tip after penetrating the skull.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26842 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1052]

Neurological Devices; Classification of Cranial Drill Handpieces (Braces)

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying cranial drill handpieces (braces) into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55683) a proposed regulation to classify drill handpieces (braces) into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. However, the agency has made minor changes to the name and identification of the device to make it clear that the rule applies to those devices that are used on a patient's skull. Separate proposed regulations will be issued later for other types of drill handpieces (e.g., dental). Accordingly, the proposed regulation is being adopted with these changes.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4325, to read as follows:

§ 882.4325 Cranial drill handpiece (brace).

(a) *Identification.* A cranial drill handpiece (brace) is a hand holder, which is used without a power source, for drills, burrs, trephines, or other cutting tools that are used on a patient's skull.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26843 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1053]

Neurological Devices; Classification of Electric Cranial Drill Motors

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying electric cranial drill motors into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectivess of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55684) a proposed regulation to classify electric drill motors into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. However, the agency has made minor changes to the name and identification of the device to make it clear that the rule applies to those devices that are used on a patient's skull. Separate proposed regulations will be issued later for other types of drill motors (e.g., dental). Accordingly, the proposed regulation is being adopted with these changes.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4360, to read as follows:

§ 882.4360 Electric cranial drill motor.

(a) *Identification.* An electric cranial drill motor is an electrically operated power source used with removable rotating surgical cutting tools or drill bits on a patient's skull.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26844 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1054]

Neurological Devices; Classification of Pneumatic Cranial Drill Motors

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying pneumatic cranial drill motors into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the

safety and effectiveness of the device. This action is being taken under the Medical Device Admendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55685) a proposed regulation to classify pneumatic drill motors into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. However, the agency has made minor changes to the name and identification of the device to make it clear that the rule applies to those devices that are used on a patient's skull. Separate proposed regulations will be issued later for other types of drill motors (e.g., dental). Accordingly, the proposed regulation is being adopted with these changes.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) a*ERR20*nd under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4370, to read as follows:

§ 882.4370 Pneumatic cranial drill motor.

(a) *Identification.* A pneumatic cranial drill motor is a pneumatically operated power source used with removable rotating surgical cutting tools or drill bits on a patient's skull.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26845 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1055]

Neurological Devices; Classification of Radiofrequency Lesion Generators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying radiofrequency lesion generators into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55685) a proposed regulation to classify radiofrequency lesion generators into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4400, to read as follows:

§ 882.4400 Radiofrequency lesion generator.

(a) *Identification.* A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26846 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1057]

Neurological Devices; Classification of Neurosurgical Headrests

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying neurosurgical headrests into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55686) a proposed regulation to classify neurosurgical headrests into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device.

Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4440, to read as follows:

§ 882.4440 Neurosurgical headrests.

(a) *Identification.* A neurosurgical headrest is a device used to support the patient's head during a surgical procedure.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26847 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1058]

Neurological Devices; Classification of Neurosurgical Head Holders (Skull Clamps)

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying neurosurgical head holders (skull clamps) into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55687) a proposed regulation to classify neurosurgical head holders (skull clamps) into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4460, to read as follows:

§ 882.4460 Neurosurgical head holder (skull clamp).

(a) *Identification.* A neurosurgical head holder (skull clamp) is a device used to clamp the patient's skull to hold head and neck in a particular position during surgical procedures.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26848 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1059]

Neurological Devices; Classification of Cranioplasty Material Forming Instruments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying cranioplasty material forming instruments into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55687) a proposed regulation to classify cranioplasty material forming instruments into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4500, to read as follows:

§ 882.4500 Cranioplasty material forming instrument.

(a) *Identification.* A cranioplasty material forming instrument is a roller used in the preparation and forming of cranioplasty (skull repair) materials.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26849 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1061]

Neurological Devices; Classification of Microsurgical Instruments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying microsurgical

instruments into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classsifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55688) a proposed regulation to classify microsurgical instruments into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4225, to read as follows:

§ 882.4525 Microsurgical instrument.

(a) *Identification.* A microsurgical instrument is a nonpowered surgical instrument used in neurological microsurgery procedures.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26850 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 882

[Docket No. 78N–1062]

Neurological Devices; Classification of Nonpowered Neurosurgical Instruments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying nonpowered neurosurgical instruments into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55689) a proposed regulation to classify nonpowered neurosurgical instruments into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4535, to read as follows:

§ 882.4535 Nonpowered neurosurgical instrument.

(a) *Identification.* A nonpowered neurosurgical instrument is a hand instrument or an accessory to a hand instrument used during neurosurgical procedures to cut, hold, or manipulate tissue. It includes specialized chisels, osteotomes, curettes, dissectors, elevators, forceps, gouges, hoods, surgical knives, rasps, scissors, separators, spatulas, spoons, blades, blade holders, blade breakers, probes, etc.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26851 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 882

[Docket No. 78N–1063]

Neurological Devices; Classification of Shunt System Implantation Instruments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying shunt system implantation instruments into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55689) a proposed regulation to classify shunt system implantation instruments into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4545, to read as follows:

§ 882.4545 Shunt system implantation instrument.

(a) *Identification.* A shunt system implantation instrument is an instrument used in the implantation of cerebrospinal fluid shunts, and includes tunneling instruments for passing shunt components under the skin.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26852 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1064]

Neurological Devices; Classification of Stereotaxic Instruments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying stereotaxic instruments into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55690) a proposed regulation to classify stereotaxic instruments into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4560, to read as follows:

§ 882.4560 Stereotaxic instrument.

(a) *Identification.* A stereotaxic instrument is a device consisting of a rigid frame with a calibrated guide mechanism for precisely positioning probes or other devices within a patient's brain, spinal cord, or other part of the nervous system.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26853 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1065]

Neurological Devices; Classification of Leukotomes

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying leukotomes into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55691) a proposed regulation to classify leukotomes into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4600, to read as follows:

§ 882.4600 Leukotome.

(a) *Identification.* A leukotome is a device used to cut sections out of the brain.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26854 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1066]

Neurological Devices; Classification of Neurosurgical Suture Needles

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying neurosurgical suture needles into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device, classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55691) a proposed regulation to classify neurosurgical suture needles into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4650, to read as follows:

§ 882.4650 Neurosurgical suture needle.

(a) *Identification.* A neurosurgical suture needle is a needle used in suturing during neurosurgical procedures or in the repair of nervous tissue.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26855 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 882

[Docket No. 78N–1067]

Neurological Devices; Classification of Cottonoid Paddies

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying cottonoid paddies into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55692) a proposed regulation to classify cottonoid paddies into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4700, to read as follows:

§ 882.4700 Cottonoid paddie.

(a) *Identification.* A cottonoid paddie is a cotton pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a) 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26856 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 882

[Docket No. 78N–1068]

Neurological Devices; Classification of Radiofrequency Lesion Probes

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying radiofrequency lesion probes into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safey and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55693) a proposed regulation to classify radiofrequency lesion probes into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by

adding new § 882.4725, to read as follows:

§ 882.4725 Radiofrequency lesion probe.

(a) *Identification.* A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26857 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1069]

Neurological Devices; Classification of Skull Punches

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying skull punches into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55693) a proposed regulation to classify skull punches into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4750, to read as follows:

§ 882.4750 Skull punch.

(a) *Identification.* A skull punch is a device used to punch holes through a patient's skull to allow fixation of cranioplasty plates or bone flaps by wire or other means.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26858 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1070]

Neurological Devices; Classification of Self-Retaining Retractors for Neurosurgery

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying self-retaining retractors for neurosurgery into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55694) a proposed regulation to classify self-retaining retractors into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

A comment objected to classifying self-retaining retractors into class II and suggested that the devices be classified instead into class I (general controls) because the devices are hand operated and the manufacturer has no way of controlling whether they are properly used. The comment also stated that there are now in effect for these devices standards that were developed by the International Standards Organization (ISO) and more meaningful standards cannot be established without a great deal of expense.

Although the agency agrees with the comment that the manufacturer cannot always prevent self-retaining retractors from being misused, the agency does not agree with and will not adopt the comment's recommendation that the device be classified into class I. The Neurological Device Classification Panel recommended that self-retaining retractors used in neurosurgery be classified into class II to protect against injuring the patient by sudden movement caused by failure of the locking mechanism on the device. The Panel did not believe that general controls would provide adequate control of this potential hazard. The agency agrees with the Panel that a performance standard is necessary for this device. If a standard that applies to this device is now in existence or is developed in the future, the agency will consider adopting it rather than developing a separate FDA standard.

The agency has made minor changes to the name of the device to make it clear that the rule applies to those self-retaining retractors that are used in neurosurgery. Separate proposed regulations that apply to other uses of self-retaining retractors will be issued later. Accordingly, the proposed regulation is being adopted with this change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by

adding new § 882.4800, to read as follows:

§ 882.4800 Self-retaining retractor for neurosurgery.

(a) *Identification.* A self-retaining retractor for neurosurgery is a self-locking device used to hold the edges of a wound open during neurosurgery.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26859 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1071]

Neurological Devices; Classification of Manual Rongeurs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying manual rongeurs into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55695) a proposed regulation to classify manual rongeurs into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

A comment objected to classifying manual rongeurs into class II and suggested that the device be classified instead into class I (general controls) because manual rongeurs are hand operated and the manufacturer has no way of controlling whether they are properly used. The comment also stated that there are now in effect for these devices standards that were developed by the International Standards Organization (ISO), and more meaningful standards cannot be established without a great deal of expense.

Although the agency agrees with the comment that manufacturers cannot always prevent the device from being misused, the agency does not agree with and will not adopt the comment's recommendation that the device be classified into class I. The Neurological Device Classification Panel recommended that manual rongeurs be classified into class II because of the need to control the device to avoid breakage of the rongeur jaws. The Panel believes that performance standards are necessary to assure that the thickness of the rongeur jaws and the material used in the construction of the device is sufficient to prevent the jaws from breaking. The Panel does not believe that general controls will provide adequate control of these characteristics of manual rongeurs. The agency agrees with the Panel that a performance standard is necessary for this device. If a standard that applies to this device is in existence or is developed in the future, however, the agency will consider adopting it rather than developing a separate FDA standard.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4840, to read as follows:

§ 882.4840 Manual rongeur.

(a) *Identification.* A manual rongeur is a manually operated instrument used for cutting or biting bone during surgery involving the skull or spinal column.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26860 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1072]

Neurological Devices; Classification of Powered Rongeurs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying powered rongeurs into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55695) a proposed regulation to classify powered rongeurs into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4845, to read as follows:

§ 882.4845 Powered rongeur.

(a) *Identification.* A powered rongeurs is a powered instrument used for cutting or biting bone during surgery involving the skull or spinal column.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26861 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1073]

Neurological Devices; Classification of Skullplate Screwdrivers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying skullplate screwdrivers into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55696) a proposed regulation to classify skullplate screwdrivers into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart E by adding new § 882.4900, to read as follows:

§ 882.4900 Skullplate screwdriver.

(a) *Identification.* A skullplate screwdriver is a tool used by the surgeon to fasten cranioplasty plates or skullplate to a patient's skull by screws.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26862 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1075]

Neurological Devices; Classification of Methyl Methacrylate for Aneurysmorrhaphy

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying methyl methacrylate for aneurysmorrhaphy into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55697) a proposed regulation to classify methyl methacrylate for aneurysmorrhaphy into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

A comment objected to classifying methyl methacrylate for aneurysmorrhaphy into class II and recommended that instead it be classified in class III. The comment pointed out that methyl methacrylate bone cement for orthopedic application has been regulated as a prescription drug and is a class III transitional device under section 520(1) of the act (21 U.S.C. 360j(l)). The comment stated that because the formulation of methyl methacrylate for aneurysmorrhaphy is identical to that of methyl methacrylate bone cement, the two devices should be regulated in the same manner.

FDA rejects the comment. Methyl methacrylate bone cement for orthopedic applications is a transitional device under section 520(1) of the act because it was subject to an approved new drug application on file with FDA prior to passage of the Medical Device Amendments of 1976. FDA disagrees that other uses of methyl methacrylate must be classified in the same manner as methyl methacrylate bone cement. Methyl methacrylate for aneurysmorrhaphy has been marketed for many years and was not regulated as a prescription drug prior to passage of the Medical Device Amendments of 1976. FDA considers methyl methacrylate for aneurysmorrhaphy to be a pre-enactment device and is classifying it into class II under section 513 of the act (21 U.S.C. 360c).

Two comments objected to the proposal to classify methyl methacrylate for aneurysmorrhaphy into class II because there is not sufficient information to establish a performance standard. One comment referred to discussions held by the Neurological Device Classification Panel during its deliberations on this device and noted that there were differences of opinion among the Panel members about the safety and effectiveness of the device. Both comments stated that the device should be classified into class III because insufficient information exists to establish a performance standard.

FDA disagrees with the comments. On May 29, 1979, the Neurological Section of the Respiratory and Nervous System Devices Panel (formerly the Neurological Device Classification Panel) met to consider all comments received on the proposal to classify methyl methacrylate for

aneurysmorrhaphy into class II. At the meeting, representatives of Howmedica, Inc., and the Health Research Group appeared before the Panel to present their views that methyl methacrylate for aneurysmorrhaphy should be classified into class III rather than class II as proposed. Representatives of the L. D. Caulk Co. and a representative of the Joint Committee on Materials, Devices, and Drugs of the American Association of Neurological Surgeons appeared before the Panel to support FDA's proposal to classify methyl methacrylate for aneurysmorrhaphy in class II.

After considering the comments and the additional testimony presented to the Panel, the Panel concluded that there is sufficient information available to establish a performance standard for the device and recommended that the classification of the device be class II as proposed. FDA agrees with the Panel and is adopting the proposed regulation without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5030, to read as follows:

§ 882.5030 Methyl methacrylate for aneurysmorrhaphy.

(a) *Identification.* Methyl methacrylate for aneurysmorrhaphy (repair of aneurysms, which are balloonlike sacs formed on blood vessels) is a self-curing acrylic used to encase and reinforce intracranial aneurysms that are not amenable to conservative management, removal, or obliteration by aneurysm clip.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

FR Doc. 79-26863 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1076]

Neurological Devices; Classification of Biofeedback Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying biofeedback devices into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55699) a proposed regulation to classify biofeedback devices into class II (performance stanadards). A period of 60 days was provided for interested persons to submit written comments to FDA.

A comment questioned whether clinical psychologists would be able to use biofeedback devices if the devices were sold only to physicians or other licensed practitioners. In particular, the comment was concerned that psychologists not be excluded from the definition of a "licensed practitioner."

Clinical psychologists are included in the definition of "licensed practitioner" because they are now licensed in all States and the District of Columbia. Unless specifically excluded by provisions of their State licenses, clinical psychologists may, therefore, purchase and use biofeedback devices.

No comments disagreed with the proposal to classify biofeedback devices in class II. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 by adding new Subpart F and § 882.5050, to read as follows:

Subpart F—Neurological Therapeutic Devices

§ 882.5050 Biofeedback device.

(a) *Identification.* A biofeedback device is an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26864 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1077]

Neurological Devices; Classification of Bite Blocks

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying bite blocks into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55700) a proposed regulation to classify bite blocks into class II (performance

standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5070, to read as follows:

§ 882.5070 Bite block.

(a) *Identification.* A bite block is a device inserted into a patient's mouth to protect the tongue and teeth while the patient is having convulsions.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26865 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1078]

Neurological Devices; Classification of Intravascular Occluding Catheters

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying intravascular occluding catheters into class III (premarket approval). The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. Each application must be submitted to FDA on or before May 28, 1982, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55700) a proposed regulation to classify intravascular occluding catheters into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5150, to read as follows:

§ 882.5150 Intravascular occluding catheter.

(a) *Identification.* An intravascular occluding catheter is a catheter with an inflatable or detachable balloon tip that is used to block a blood vessel to treat malformations, e.g., aneurysms (balloonlike sacs formed on blood vessels) of intracranial blood vessels.

(b) *Classification.* Class III (premarket approval).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26866 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1079]

Neurological Devices; Classification of Carotid Artery Clamps

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying carotid artery clamps into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55701) a proposed regulation to classify carotid artery clamps into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5175, to read as follows:

§ 882.5175 Carotid artery clamp.

(a) *Identification.* A carotid artery clamp is a device that is surgically placed around a patient's carotid artery (the principal artery in the neck that supplies blood to the brain) and has a removable adjusting mechanism that protrudes through the skin of the patient's neck. The clamp is used to occlude the patient's carotid artery to treat intracranial aneurysms (balloonlike sacs formed on blood vessels) or other intracranial vascular malformations that are difficult to attach directly by reducing the blood pressure and blood flow to the aneurysm or malformation.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26867 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1080]

Neurological Devices; Classification of Aneurysm Clips

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying aneurysm clips into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55703) a proposed regulation to classify aneurysm clips into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

A comment from a manufacturer suggested that aneurysm clips be classified in class III (premarket approval) instead of class II (performance standards) as proposed. The comment stated that aneurysm clips are critical, life-sustaining devices and that simple performance standards are not sufficient for these types of instruments.

The agency disagrees with this comment. The comment supplied no additional data or documentation that was not considered by the agency before publishing the proposal to classify aneurysm clips into class II. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5200, to read as follows:

§ 882.5200 Aneurysm clip.

(a) *Identification.* An aneurysm clip is a device used to occlude an intracranial aneurysm (a balloonlike sac formed on a blood vessel) to prevent it from bleeding or bursting.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26868 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1081]

Neurological Devices; Classification of Implanted Malleable Clips

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying implanted malleable clips into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55704) a proposed regulation to classify implanted malleable clips into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

One comment agreed with the proposal to classify implanted malleable clips in class II. The comment also agreed with the recommendation of the Neurological Device Classification Panel that sterling silver not be used in implanted malleable clips. The comment suggested that a performance standard should exclude the use of sterling silver as a material for implanted malleable clips.

The agency agrees that a performance standard should exclude the use of sterling silver as a material for implanted malleable clips. At a future date, the agency will initiate proceedings to adopt performance standards for this device, as well as for other devices that are classified in class II.

A comment from a manufacturer suggested that implanted malleable clips be classified in class III (premarket approval) instead of class II (performance standards) as proposed. The comment stated that these clips are critical, life-sustaining devices and simple performance standards are not sufficient for these types of devices.

The agency disagrees with the comment to classify implanted malleable clips in class III. The comment supplied no additional data or documentation that was not considered by the agency before publishing the proposal to classify the device in class II.

The agency has made minor changes to the identification of the device to make it clear that the rule applies to those implanted malleable clips intended primarily for intracranial use. Accordingly, the proposed regulation is being adopted with this change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by

adding new § 882.5225, to read as follows:

§ 882.5225 Implanted malleable clip.

(a) *Identification.* An implanted malleable clip is a bent wire or staple that is forcibly closed with a special instrument to occlude an intracranial blood vessel or aneurysm (a balloonlike sac formed on a blood vessel), stop bleeding, or hold tissue or a mechanical device in place in a patient.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26869 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1082]

Neurological Devices; Classification of Aversive Conditioning Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying aversive conditioning devices into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55705) a proposed regulation to classify aversive conditioning devices into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5235, to read as follows:

§ 882.5235 Aversive conditioning device.

(a) *Identification.* An aversive conditioning device is an instrument used to administer an electrical shock or other noxious stimulus to a patient to modify undesirable behavioral characteristics.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26870 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1083]

Neurological Devices; Classification of Burr Hole Covers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying burr hole covers into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55706) a proposed regulation to classify burr hole covers into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5250, to read as follows:

§ 882.5250 Burr hole cover.

(a) *Identification.* A burr hole cover is a plastic or metal device used to cover or plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26871 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1084]

Neurological Devices; Classification of Nerve Cuffs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying nerve cuffs into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken

under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55707) a proposed regulation to classify nerve cuffs into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

Three comments were received. The comments disagreed with classifying nerve cuffs in class III. Two of the comments were from physicians, who described their successful experiences with the device in repairing nerves and in capping the ends of nerves to prevent and treat painful neuromas (tumors). Both physicians stated that the nerve cuff is useful in protecting severed nerves in patients who have wounds with massive scarring, e.g., wounds due to gunshot wounds, and in treating and preventing the occurrence of neuromas on nerves in extremities that have been amputated. One of the physicians cited a recent study (Swanson, et al., *The Journal of Hand Surgery*, 2:70–78, 1977) of the effectiveness of nerve capping in the treatment and prevention of amputation neuromas. The study reported on the results of capping 38 nerves in the upper extremities of 18 patients and 9 nerves in the lower extremities of 8 patients. One patient required a second operation to recap a nerve for successful relief of pain, and two patients were considered failures.

A comment from Dow Corning Corporation (DOW), a manufacturer of the nerve cuff, included an extensive bibliography of references relative to the use of the nerve cuff in humans and in animals, including the study by Swanson mentioned above. The comment argued that the proposal to classify nerve cuffs in class III relied too heavily on one journal article (Szal and Miller, *Archives of Otolaryngology*, 101:160–165, 1975) that showed negative results when nerve cuffs were used to protect nerve repair sites in rabbits. The comment noted that many other investigators have consistently reported that nerve cuffs are effective and that the Szal study was not relevant to the clinical use of the nerve cuff because the wrong size nerve cuffs were used on the facial nerves of rabbits.

On February 23, 1979, the Neurological Section of the Respiratory and Nervous System Devices Panel (formerly the Neurological Device Classification Panel) met to review the comments received on the proposal to classify nerve cuffs in class III. At the meeting, representatives of Dow presented a brief history of the device and described the manner in which it is currently being used. They stated that the nerve cuff has been used extensively to treat war injuries, but that it was only being marketed on a small scale today. They noted that neuromas were prevented in all but about 5 percent of the cases reported by Swanson in his study. The firm also noted that neuromas normally occur in 30 percent of such cases. The Dow representative asked the Panel to recommend that the device be classified in class II because of its long history of use without adverse reports.

During the Panel discussion, one of the Panel members pointed out that the literature from the 1960's pertaining to the nerve cuff was enthusiastic, but that the use of the device has largely been displaced by improvements in surgical technique. The member also pointed out that the effectiveness of nerve cuffs in nerve repair was not always good and that the results were sometimes disappointing. Although several Panel members disagreed with classifying nerve cuffs in class II because the device is of questionable effectiveness when used as a sheath in repairing nerves, the majority of the Panel members voted to recommend that the classification of nerve cuffs be changed to class II. Those Panel members favoring class II noted that the data showed that the device is effective in capping the ends of nerves to prevent neuromas and that the device could be beneficial in the absence of microsurgical techniques.

FDA has carefully considered the Panel's recommendation and the additional information and data submitted on this device. FDA agrees with the Panel and is changing the classification of nerve cuffs in the final rule to class II rather than class III as proposed. The agency realizes that the nerve cuff may not be as effective in repairing nerves as newer techniques involving microsurgery. However, the data appear to demonstrate the effectiveness of the device as a nerve cap in preventing neuromas and its usefulness as a sheath to protect the nerve during nerve repair when the recommended size nerve cuff is used. Accordingly, the final regulation is being changed to classify the device in class II. For the reasons stated in the general regulation on neurological devices, published elsewhere in this issue of the **Federal Register**, FDA does not believe that it is necessary to issue a new proposal concerning this decision. Persons who disagree with classifying nerve cuffs in class II may petition for reclassification of the device under Subpart C of Part 860, the classification procedures regulation.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5275, to read as follows:

§ 882.5275 Nerve cuff.

(a) *Identification.* A nerve cuff is a tubular silicone rubber sheath used to encase a nerve for aid in repairing the nerve (e.g., to prevent ingrowth of scar tissue) and for capping the end of the nerve to prevent the formation of neuroma (tumors).

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26872 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1085]

Neurological Devices; Classification of Methyl Methacrylate for Cranioplasty

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying methyl methacrylate for cranioplasty into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55708) a proposed regulation to classify methyl methacrylate for cranioplasty into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

A comment objected to classifying methyl methacrylate for cranioplasty into class II and recommended that instead it be classified into class III. The comment pointed out that methyl methacrylate bone cement for orthopedic applications has been regulated as a prescription drug and is a class III transitional device under section 520(1) of the act (21 U.S.C. 360J(l)). The comment stated that because the formulation of methyl methacrylate for cranioplasty is identical to that of methyl methacrylate bone cement, the two devices should be regulated in the same manner.

FDA rejects the comment. Methyl methacrylate bone cement for orthopedic applications is a transitional device under section 520(1) of the act because it was subject to an approved new drug application on file with FDA prior to passage of the Medical Device Amendments of 1976. FDA disagrees that other uses of methyl methacrylate must be classified in the same manner as methyl methacrylate bone cement. Methyl methacrylate for cranioplasty has been marketed for many years and was not regulated as a prescription drug prior to passage of the Medical Device Amendments of 1976. FDA considers methyl methacrylate for cranioplasty to be a pre-enactment device and is classifying it into class II under section 513 of the act (21 U.S.C. 360c).

A comment objected to the proposal to classify methyl methacrylate for cranioplasty into class II because there is not sufficient information to establish a performance standard and recommended that it be classified instead into class III.

FDA disagrees with the comment. On May 29, 1979, the Neurological Section of the Respiratory and Nervous Systems Devices Panel (formerly the Neurological Device Classification Panel) met to consider all comments received on the proposal to classify methyl methacrylate for cranioplasty into class II. At the meeting, representatives of Howmedica, Inc., appeared before the Panel to present their views that methyl methacrylate for cranioplasty should be classified into class III rather than class II as proposed. Representatives of the L. D. Caulk Co. and a representative of the Joint Committee on Materials, Devices, and Drugs of the American Association of Neurological Surgeons appeared before the Panel to support FDA's proposal to classify methyl methacrylate for cranioplasty into class II.

After considering the comments and the additional testimony presented to the Panel, the Panel concluded that there is sufficient information available to establish a performance standard for the device and recommended that the classification of the device be class II as proposed. FDA agrees with the Panel and is adopting the proposed regulation without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5300, to read as follows:

§ 882.5300 Methyl methacrylate for cranioplasty.

(a) *Identification.* Methyl methacrylate for cranioplasty (skull repair) is a self-curing acrylic that a surgeon uses to repair a skull defect in a patient. At the time of surgery, the surgeon initiates polymerization of the material and forms it into a plate or other appropriate shape to repair the defect.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

FR Doc. 79–26873 Filed 9–31–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 882

[Docket No. 78N–1066]

Neurological Devices; Classification of Preformed Alterable Cranioplasty Plates

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying preformed alterable cranioplasty plates into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55709) a proposed regulation to classify preformed alterable cranioplasty plates into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5320, to read as follows:

§ 882.5320 Preformed alterable cranioplasty plate.

(a) *Identification.* A preformed alterable cranioplasty plate is a device that is implanted into a patient to repair a skull defect. It is constructed of a

material, e.g., tantalum, that can be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26874 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1087]

Neurological Devices; Classification of Preformed Nonalterable Cranioplasty Plates

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying preformed nonalterable cranioplasty plates into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55711) a proposed regulation to classify preformed nonalterable cranioplasty plates into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5330, to read as follows:

§ 882.5330 Preformed nonalterable cranioplasty plate.

(a) *Identification.* A preformed nonalterable cranioplasty plate is a device that is implanted in a patient to repair a skull defect and is constructed of a material, e.g., stainless steel or vitallium, that cannot be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26875 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1088]

Neurological Devices; Classification of Cranioplasty Plate Fasteners

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying cranioplasty plate fasteners into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55712) a proposed regulation to classify cranioplasty plate fasteners into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5360, to read as follows:

§ 882.5360 Cranioplasty plate fastener.

(a) *Identification.* A cranioplasty plate fastener is a screw, wire, or other article made of tantalum, vitallium, or stainless steel used to secure a plate to the patient's skull to repair a skull defect.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26876 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1089]

Neurological Devices; Classification of Lesion Temperature Monitors

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying lesion temperature monitors into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55713) a proposed regulation to classify lesion temperature monitors into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5500, to read as follows:

§ 882.5500 Lesion temperature monitor.

(a) *Identification.* A lesion temperature monitor is a device used to monitor the tissue temperature at the site where a lesion (tissue destruction) is to be made when a surgeon uses a radiofrequency (RF) lesion generator and probe.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26877 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 882

[Docket No. 78N–1090]

Neurological Devices; Classification of Central Nervous System Fluid Shunts and Components

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying central nervous system fluid shunts and components into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55714) a proposed regulation to classify central nervous system fluid shunts and components into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

One comment objected to classifying central nervous system fluid shunts and components into class II (performance standards) and suggested that the device be classified into class III instead because not enough information exists to establish a performance standard.

The comment did not submit any additional data or information that was not considered by the agency before publishing the proposal to classify central nervous system fluid shunts and components into class II. Therefore, the agency rejects this comment.

A comment agreed with the proposal to classify implanted or partially implanted central nervous system fluid shunts and components into class II, but suggested that all components that are external to the patient (e.g., cerebrospinal fluid (CSF) collection bags) be classified into class I. The comment stated that medical costs could be reduced if bags designed for other purposes could be used for external CSF collection.

The agency has carefully considered this comment and has decided to classify all central nervous system fluid shunts and components in class II as proposed. The agency does not believe that classification of the device into class II will prevent the user from using other types of bags that were not specifically designed for CSF collection. The agency believes, however, that components specifically promoted for this purpose should be appropriate for the application and compatible with the other components used for central nervous system fluid shunting. The agency does not anticipate that a detailed performance standard for every component will be necessary. However, it does believe that a standard for central nervous system fluid shunt and components should address the compatibility of each component to the functioning of the overall system. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5550, to read as follows:

§ 882.5550 Central nervous system fluid shunts and components.

(a) *Identification.* A central nervous system fluid shunt is a device or combination of devices used to divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial pressure or fluid volume (e.g., due to hydrocephalus). Components of a central nervous system shunt include catheters, valved catheters, valves, connectors, and other accessory components intended to facilitate use of the shunt or evaluation of a patient with a shunt.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26878 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1091]

Neurological Devices; Classification of Cranial Electrotheraphy Stimulators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying cranial electrotheraphy stimulators into class III (premarket approval). The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. Each application must be submitted to FDA on or before May 28, 1982, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55716) a proposed regulation to classify cranial electrotheraphy stimulators into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5800, to read as follows:

§ 882.5800 Cranial electrotheraphy stimulator.

(a) *Identification.* A cranial electrotheraphy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety.

(b) *Classification.* Class III (premarket approval).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26879 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1092]

Neurological Devices; Classification of External Functional Neuromuscular Stimulators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying external functional neuromuscular stimulators into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55717) a proposed regulation to classify external functional neuromuscular stimulators into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5810, to read as follows:

§ 882.5810 External functional neuromuscular stimulator.

(a) *Identification.* An external functional neuromuscular stimulator is an electrical stimulator that uses external electrodes for stimulating muscles in the leg and ankle of partially paralyzed patients (e.g., after stroke) to provide flexion of the foot and thus improve the patient's gait.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26880 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1093

Neurological Devices; Classification of Implanted Cerebellar Stimulators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying implanted cerebellar stimulators into class III (Premarket approval). The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. Each application must be submitted to FDA on or before May 28, 1982, or 90 days after promulgation of a separate regulation requiring premarket

approval of the device, whichever occurs later. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55718) a proposed regulation to classify implanted cerebellar stimulators into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

One comment disagreed with the proposal to classify implanted cerebellar stimulators in class III. The comment recommended that cerebellar stimulators for use in the treatment of spasticity be classified instead in class II because personal experience with over 100 patients had proven the safety and effectiveness of the device.

The Neurological Device Classification Panel received extensive testimony and data on cerebellar stimulation and concluded that insufficient information exists to establish a performance standard that would assure the safety and effectiveness of the device. The Panel, therefore, recommended that the device undergo premarket approval to assure that it is safe and effective. The comment received on the proposal to classify implanted cerebellar stimulators in class III did not provide additional data to show that a performance standard can be established that would assure the safety and effectiveness of implanted cerebellar stimulators. Therefore, the agency rejects the comment and is adopting the proposed regulation without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5820, to read as follows:

§ 882.5820 Implanted cerebellar stimulator.

(a) *Identification.* An implanted cerebellar stimulator is a device used to stimulate electrically a patient's cerebellar cortex for the treatment of intractable epilepsy, spasticity, and some movement disorders. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's cerebellum and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26881 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1094]

Neurological Devices; Classification of Implanted Diaphragmatic/Phrenic Nerve Stimulators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying implanted diaphragmatic/phrenic nerve stimulators into class III (premarket approval). The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. Each application must be submitted to FDA on or before May 28, 1982, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55719) a proposed regulation to classify implanted diaphragmatic/phrenic nerve stimulators into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

The following is a summary of the comments received and the agency's responses to them:

1. One comment stated that this device should now be classified into class III so that manufacturers and users who are unfamiliar with the device will realize the need for caution in its construction and its application. The comment stated, however, that the device, as currently constructed, is reasonably safe and effective and that the principal risk to the patient is not from device failure but from the failure of the user to appreciate the indications for diaphragm pacing and from failure to apply the device properly.

FDA agrees with this comment.

2. A comment pointed out that the Neurological Device Classification Panel gave as a reason for classifying this device in class III the fact that available data on the device were from only one company. The comment stated that whether the device is available from one or more sources has no bearing on its safety and efficacy and enclosed a select bibliography of 59 references on diaphragm stimulation.

FDA agrees that the availability of a device from only one company does not mean that the device is not safe or effective. The Neurological Device Classification Panel did not recommend that this device be classified into class III solely because it is available from only one company. However, the Panel did cite this fact as one reason for believing that insufficient information is available to establish a performance standard for the device that will assure its safety and effectiveness. Because this device is a life-sustaining implant, the Federal Food, Drug, and Cosmetic Act requires that FDA classify it into class III if insufficient information is available to establish a performance standard that will assure the safety and effectiveness of the device. In this case, the agency concurs with the Panel that insufficient information exists to establish such a performance standard.

3. A comment was received regarding the risks to health identified by the Panel. The comment stated that device failure can be minimized, although not totally prevented, by using high quality components and production techniques and that the consequences of a catastrophic device failure can be ameliorated by using patient monitoring and device redundancy. The comment

also stated that the materials that are used to construct the device have been used in several thousand other patients and have been shown to be tissue compatible. The comment also noted that injury to the phrenic nerve in patients in whom the device has been implanted has been associated with the surgical technique rather than with the electrical stimulation of the device and that patients have used the device for up to 9 years without evidence of injury to the phrenic nerve.

FDA recognizes that the risks to health identified by the Panel will not occur in every patient. However, those risks to health are hazards that the patient is exposed to when the device is implanted and used. Obviously, in most patients, the benefits to be gained from using the device far outweigh the risks to which the patient is exposed. However, the risks to health do exist and should be regulated in the most effective possible way.

Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5830, to read as follows:

§ 882.5830 Implanted diaphragmatic/phrenic nerve stimulator.

(a) *Identification.* An implanted diaphragmatic/phrenic nerve stimulator is a device that provides electrical stimulation of a patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hyperventilation (a state in which an abnormally low amount of air enters the lungs) caused by brain stem disease, high cervical spinal cord injury, or chronic lung disease. The stimulator consists of an implanted receiver with electrodes that are placed around the patient's phrenic nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26882 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1095]

Neurological Devices; Classification of Implanted Intracerebral/Subcortical Stimulators for Pain Relief

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying implanted intracerebral/subcortical stimulators for pain relief into class III (premarket approval). The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. Each application must be submitted to FDA on or before May 28, 1982, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55720) a proposed regulation to classify implanted intracerebral/subcortical stimulators for pain relief into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

The following is a summary of the comments and the agency's responses to them:

1. Several comments asked that the implanted intracerebral/subcortical stimulator for pain relief not be classified into class III because this would make it more difficult for patients to get the device and for neurosurgeons to use it. Several comments also said that the device should not be classified into class III because brain stimulation for pain relief is no longer an experimental procedure and should be standard treatment.

The agency disagrees with the comments. Classifying a device into class III does not necessarily mean that the device will be more difficult to obtain and does not imply that it is an experimental device. Each manufacturer of a device classified into class III will have at least 30 months after the effective date of the final regulation classifying the device into class III to submit to FDA an application for approval of the device. Manufacturers may continue marketing the device during the 30-month period. If a manufacturer's application is approved, the manufacturer can continue marketing the device indefinitely. FDA believes that 30 months is sufficient time for manufacturers to document the safety and effectiveness of their devices and to submit an application for approval. If at the end of 30 months a manufacturer does not have sufficient safety and effective data to support an application for approval, FDA may authorize continued distribution of the device for investigational purposes, as provided in section 520(g) of the act (21 U.S.C. 360j(e)).

2. Several comments stated that the device should be classified into class II because there is sufficient clinical experience with the device to demonstrate that it is safe and effective. However, one comment agreed with classifying the device into class III and stated that long-term effectiveness of the device has not been proven.

The agency does not agree that the device should be classified into class II. Although there have been several reports of successful clinical application of the device, FDA does not believe that there is sufficient information to develop a performance standard that will assure that marketed devices are safe and effective. The available data contain little information that can be used in developing a performance standard. FDA believes that the only way to assure that implanted intracerebral/subcortical stimulators for pain relief are safe and effective is to classify the device into class III so that each manufacturer will be required to document the safety and effectiveness of the device that the manufacturer markets.

3. Several comments stated that the risks of using the device are minimal

and that the complication rate has been low. One comment stated that the platinum electrodes that are used cause almost no tissue reaction. Two comments stated that the risks of injuring brain tissue while inserting the device electrodes into the brain are no greater than the risks involved in using some other widely accepted neurosurgical procedures. Another comment stated that the devices use safe levels of electrical current. The comments suggested that, for these reasons, the device should be classified into class II instead of class III.

The agency does not agree that the risks to health from this device are minimal and that the device should be classified into class II. FDA realizes that the risks associated with this device may be presented by other accepted neurosurgical procedures and may not result in patient injury in every case. Patients are, however, exposed to potentially serious risks when the device is used. Obviously, the benefits to the patient must be balanced against these risks before the device is used. If a particular device is unreliable or ineffective, patients may be exposed to risks needlessly. FDA believes that the implanted intracerebral/subcortical stimulator for pain relief must be classified into class III to require manufacturers of the device to demonstrate that their device is reasonably safe and effective for this use. Accordingly, the proposed rule is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5840, to read as follows:

§ 882.5840 Implanted intracerebral/subcortical stimulator for pain relief.

(a) *Identification.* An implanted intracerebral/subcortical stimulator for pain relief is a device that applies electrical current to subsurface areas of a patient's brain to treat severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed within a patient's brain and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26883 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1096]

Neurological Devices; Classification of Implanted Spinal Cord Stimulators for Bladder Evacuation

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying implanted spinal cord stimulators for bladder evacuation into class III (premarket approval). The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. Each application must be submitted to FDA on or before May 28, 1982, or 90 days after promulgation separate regulation requiring premarket approval of the device, whichever occurs later. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55721) a proposed regulation to classify implanted spinal cord stimulators for bladder evacuation into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5850, to read as follows:

§ 882.5850 Implanted spinal cord stimulator for bladder evacuation.

(a) *Identification.* An implanted spinal cord stimulator for bladder evacuation is an electrical stimulator used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is unable to empty his or her bladder by reflex means or by the intermittent use of catheters. The stimulator consists of an implanted receiver with electrodes that are placed on the conus medullaris portion of the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26884 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1097]

Neurological Devices; Classification of Implanted Neuromuscular Stimulators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying implanted neuromuscular stimulators into class III (premarket approval). The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. Each application must be submitted to FDA on or before May 28, 1982, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55722) a proposed regulation to classify implanted neuromuscular stimulators into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5860, to read as follows:

§ 882.5860 Implanted neuromuscular stimulator.

(a) *Identification.* An implanted neuromuscular stimulator is a device that provides electrical stimulation to a patient's peroneal or femoral nerve to cause muscles in the leg to contract, thus improving the gait in a patient with a paralyzed leg. The stimulator consists of an implanted receiver with electrodes that are places around a patient's nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver. The external transmitter is activated by a switch in the heel in the patient's shoe.

(b) *Classification.* Class III (premarket approval).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–26885 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1098]

Neurological Devices; Classification of Implanted Peripheral Nerve Stimulators for Pain Relief

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying implanted peripheral nerve stimulators for pain relief into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55724) a proposed regulation to classify implanted peripheral nerve stimulators for pain relief into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

Several comments agreed with classifying implanted peripheral nerve stimulators for pain relief in class II. One comment recommended that the device be classified into class III (premarket approval), but no new information was submitted to support the recommendation.

Accordingly, the agency rejects the comment and is adopting the proposed regulation without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5870, to read as follows:

§ 882.5870 Implanted peripheral nerve stimulator for pain relief.

(a) *Identification.* An implanted peripheral nerve stimulator for pain relief is a device that is used to stimulate electrically a peripheral nerve in a patient to relieve severe intractable pain. The stimulator consists of an inplanted receiver with electrodes that are placed around a peripheral nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

FR Doc. 79–26886 Filed 8–31–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 882

[Docket No. 78N–1099]

Neurological Devices; Classification of Implanted Spinal Cord Stimulators for Pain Relief

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying implanted spinal cord stimulators for pain relief into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of

November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55725) a proposed regulation to classify implanted spinal cord stimulators for pain relief into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

Several comments were received regarding the use of this device for treating conditions other than pain, such as multiple sclerosis or other motor disorders. One comment suggested that the device category be broadened to include indications other than pain relief, or that a separate category for implanted spinal cord stimulators for motor disorders be created.

The agency disagrees that this device category should include devices that are indicated for uses other than pain relief. The proposed neurological device classification regulations that FDA published will apply to those neurological devices that were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. New devices introduced for marketing after May 28, 1976, or devices that have been substantially altered (e.g., by providing new indications in the labeling), are by law automatically classified into class III and must undergo premarket approval prior to marketing. The agency believes that implanted spinal cord stimulators for motor disorders were distributed by manufacturers before May 28, 1976 only for investigational purposes and were not being "marketed." Because the implanted spinal cord stimulator for motor disorder indications is not a "pre-enactment" device and will be automatically classified into class III, the Panel did not recommend, and FDA did not propose, a separate classification category for this use. Manufacturers who now desire to distribute, for other than investigational purposes, an implanted spinal cord stimulator that includes labeling with indications for motor disorders must submit to FDA a premarket approval application or petition the agency to reclassify the device for this new indication.

Several comments agreed with the agency's proposal to classify implanted spinal cord stimulators for pain relief into class II.

Two comments disagreed with classifying the device into class II. One comment suggested that the device be classified into class I (general controls), but offered no reason for the recommendation other than stating that the collective experience of many surgeons justified classification of the device into class I. The other comment suggested that the device be classified into class III rather than class II because there is not sufficient information to develop a performance standard. The comment did not supply any additional information or explain the basis for the suggestion. Therefore, the agency disagrees with both comments and is adopting the proposed regulation without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5880, to read as follows:

§ 882.5880 Implanted spinal cord stimulator for pain relief.

(a) *Identification.* An implanted spinal cord stimulator for pain relief is a device that is used to stimulate electrically a patient's spinal cord to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William R. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26887 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1100]

Neurological Devices; Classification of Transcutaneous Electrical Nerve Stimulators for Pain Relief

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying transcutaneous electrical nerve stimulators for pain relief into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55726) a proposed regulation to classify transcutaneous electrical nerve stimulators for pain relief into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5890, to read as follows:

§ 882.5890 Transcutaneous electrical nerve stimulator for pain relief.

(a) *Identification.* A transcutaneous electrical nerve stimulator for pain relief is a device used to apply an electrical current to electrodes on a patient's skin to treat pain.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

FR Doc. 79-26888 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1101]

Neurological Devices; Classification of Preformed Craniosynostosis Strips

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying preformed craniosynostosis strips into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55727) a proposed regulation to classify preformed craniosynostosis strips into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5900, to read as follows:

§ 882.5900 Preformed craniosynostosis strip.

(a) *Identification.* A preformed craniosynostosis strip is a plastic strip used to cover bone edges of craniectomy sites (sites where the skull has been cut) to prevent the bone from regrowing in patients whose skull sutures are abnormally fused together.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

FR Doc. 79-26889 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1102]

Neurological Devices; Classification of Dura Substitutes

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying dura substitutes into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55728) a proposed regulation to classify dura substitutes into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5910, to read as follows:

§ 882.5910 Dura substitute.

(a) *Identification.* A dura substitute is a sheet or material that is used to repair the dura mater (the membrane surrounding the brain).

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26890 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1103]

Neurological Devices; Classification of Electroconvulsive Therapy Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying electroconvulsive therapy devices into class III (premarket approval). The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. Each application must be submitted to FDA on or before May 28, 1982, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification

procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55729) a proposed regulation to classify electroconvulsive therapy devices into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

Several comments were received from patients who had been treated with electroconvulsive therapy (ECT). The comments complained of loss of memory after receiving the ECT treatments and asked for strict controls over the application of ECT. Several other comments disagreed with the proposal to classify ECT devices in class II and recommended that they be classified in class III. One of the comments stated that there is insufficient information available to develop a performance standard for ECT devices in the following areas: (1) The proper wave form to be used; (2) The amount of energy to be applied; (3) The size and shape of the electrodes; (4) The characteristics of the skin/electrode interface. Another comment stated that ECT is, by its nature, brain damaging and, because there is no consensus regarding the effectiveness of the therapy, disagreed that the FDA can "assure effectiveness" of ECT. Another comment agreed with the proposal to classify ECT devices in class II and pointed out that the American Psychiatric Association (APA) has initiated efforts to develop a performance standard for ECT devices.

On May 29, 1979, the Neurological Section of the Respiratory and Nervous System Devices Panel (formerly the Neurological Device Classification Panel) met to consider the comments that were received on the proposal to classify electroconvulsive therapy devices in class II. At the meeting, a representative of the Health Research Group asked that ECT devices be classified in class III because insufficient information is available to develop a performance standard. A representative of the Citizen's Commission on Human Rights of the Association of Scientologists for Reform, claimed that ECT is neither safe nor effective for any use and called for its abolition. A patient described her personal experience with ECT and stated that she had severe memory loss because of the treatment. Richard Weiner, M.D., Ph. D., described the goals and purposes of a committee formed by the American Psychiatric Association (APA) at the request of FDA to develop standards for electroconvulsive therapy devices. Dr. Weiner stated that the committee is reviewing the literature to gather information on which to base a performance standard, and that he expected to have sufficient information to begin writing the standard in about six months.

The Panel's discussion centered around the question of whether there is now sufficient information to develop an adequate performance standard for electroconvulsive therapy devices. There was disagreement over what constitutes sufficient information; and several panel members expressed doubt that enough information does, in fact, exist and noted that such information was not available to them. The Panel therefore voted to recommend that ECT devices be classified in class III rather than class II as proposed, because there is not now enough information available on which to establish a performance standard for ECT devices.

FDA has carefully considered the classification of electroconvulsive therapy devices and has decided to classify the devices in class III rather than class II as proposed. FDA is aware of and encourages the work of the APA committee in developing a performance standard. The agency is persuaded, however, based on the comments received on the proposal and on the recommendation of the Panel, that there is insufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the ECT device. This conclusion, which differs from the preliminary judgment contained in the proposed regulation, was prompted by FDA's belief that the characteristics of ECT devices that should be addressed in a standard have not been identified precisely enough for the agency to determine whether adequate information is available to write a standard. Accordingly, the agency believes that ECT devices should be classified in class III until the APA committee has completed its review of ECT, has identified the characteristics of ECT devices that should be controlled by a performance standard, and has found that sufficient information exists to establish an adequate standard. FDA encourages the committee to submit its conclusions, a proposed standard, and the information on which the standard is based to FDA, along with a petition to reclassify ECT devices into class II.

Accordingly, the final regulation for electroconvulsive therapy devices is being changed to classify the device in class III instead of class II as proposed. For the reasons stated in the general regulation on neurological devices, published elsewhere in this issue of the **Federal Register**, FDA does not believe that it is necessary to issue a new proposal concerning this decision. Persons who disagree with classifying electroconvulsive therapy devices in class III may petition for reclassification of the device under Subpart C of Part 860, the classification procedures regulation.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5940, to read as follows:

§ 882.5940 Electroconvulsive therapy device.

(a) *Identification.* An electroconvulsive therapy device is a device used for treating severe psychiatric disturbances (e.g., severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head.

(b) *Classification.* Class III (premarket approval).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26891 Filed 8-31-79; 8:45 am]

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21 CFR Part 882

[Docket No. 78N-1104]

Neurological Devices; Classification of Artificial Embolization Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying artificial embolization devices into class III (premarket approval). The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. Each application must be submitted to FDA on or before May 28, 1982, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. This action is being taken

under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55730) a proposed regulation to classify artificial embolization devices into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

One comment recommended that artificial embolization devices be classified in class II rather than III because the devices have been used for 15 years and the safety of their use has been established. The comment noted that the safety of artificial embolization devices depends more on the experience of the user than on the device itself. The comment also pointed out that although the use of the device is associated with major risks of neurological damage, the disease process being treated is also associated with high morbidity and mortality.

The agency agrees that the safety of artificial embolization devices depends on the skill of the user as well as on the device itself. However, the comment did not supply additional information that was not considered by the Neurological Device Classification Panel and FDA in developing the proposed classification regulation. Therefore, the agency disagrees that artificial embolization devices should be classified in class II. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5950, to read as follows:

§ 882.5950 Artificial embolization device.

(a) *Identification.* An artificial embolization device is an object that is placed in a blood vessel to permanently obstruct blood flow to an aneurysm or other vascular malformation.

(b) *Classification.* Class III (premarket approval).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

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21 CFR Part 882

[Docket No. 78N–1105]

Neurological Devices; Classification of Skull Tongs for Traction

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying skull tongs for traction into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55731) a proposed regulation to classify skull tongs for traction into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 882 in Subpart F by adding new § 882.5960, to read as follows:

§ 882.5960 Skull tongs for traction.

(a) *Identification.* A skull tongs for traction is an instrument used to immobilize a patient with a cervical spine injury (e.g., fracture or dislocation). The device is caliper shaped with tips that penetrate the skin. It is anchored to the skull and has a heavy weight attached to it that maintains, by traction, the patient's position.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 4, 1979.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).)

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

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